How to Increase Colorectal Cancer Screening Rates in Practice:

A Primary Care Clinician's* Evidence-Based Toolbox and Guide 2008

**Including Family Physicians, General Internists, Obstetrician-Gynecologists, Nurse Practitioners, Physician Assistants, and their Office Managers*

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American Cancer Society®

National Colorectal Cancer Roundtable

Thomas Jefferson University

Avoid These Errors:

- ✗ Patients are screened for colorectal cancer (CRC) with only a digital rectal exam.[1]
- ✗ Patients are screened for CRC in the office with a single sample from a stool blood test.[2]
- ✗ Patients with a history of adenomatous polyps in a first-degree relative are not identified as people at increased risk.[3,4]
- ✗ Providers have cultural assumptions that inhibit frank discussion, which leads to a clear recommendation for screening.
- ✗ Patients with a positive FOBT, FIT, stool DNA, CT colonography, double-contrast barium enema, or flexible sigmoidoscopy never receive an order for a complete diagnostic exam.[5]
- ✗ There is no follow up on patients referred for a complete diagnostic exam.[6]
- ✗ Practitioners recommend screening with colonoscopy for those at average risk more often than every 10 years or CT colonography, double-contrast barium enema, or flexible sigmoidoscopy more often than every five years.
- ✗ Screening is started earlier than age 50 for average-risk asymptomatic individuals.

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Disclaimer

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September 2008

Dear Colleague,

Like you, we are primary care physicians who have experienced the many changes in primary care medicine over recent years. While the burdens on primary care practitioners are greater than ever before, the need for effective primary care practice is just as great. Screening for colorectal cancer, like other highly effective preventive measures, is one of the essential elements of primary care practice. This publication is similar to other continuing medical education bulletins you receive, but the intended outcome is different. The outcome here is improved office practice. This is designed to help you and your office manager organize your practice so that every appropriate patient walks out of the door with the needed recommendation.

While the overwhelming majority of primary care doctors screen for colorectal cancer and other cancers, few would say that every eligible patient leaves the practice with the needed recommendation. It is not enough to know what needs to be done. It is *doing* it that makes a difference. This guide contains evidence-based tools and strategies that can move your practice to a higher level of performance. We have assembled materials we wish we had available as we worked toward improving screening rates in our respective communities. While screening may not be at the top of a patient's lists of concerns when he/she walks through the door, recommendations from the patients' doctors are the most effective way to ensure that every age-appropriate individual gets screened. Abundant research supports this statement. It is essential to get this simple truth to primary care doctors around the country.

There are many misconceptions about colorectal cancer screening. One of the most destructive is that patients do not want to be screened. There is hard evidence from several studies that this is untrue. Some physicians might not be aware of how much evidence has accumulated that screening procedures prevent cancers and save lives. Solid projections are that incidence and mortality will drop significantly with widespread screening.

We hope that you, your practice, and your patients benefit from the materials in this guide. Continuing medical education credit is now available from the American Medical Association, the American Academy of Family Physicians, the American Board of Internal Medicine, and other organizations for practice-improvement activities like those described in this guide. See inside for details. A Web-based version is also available.

Sincerely,

Richard C. Wender

Richard Wender, MD

Mona Sarfaty

Mona Sarfaty, MD

NATIONAL COLORECTAL CANCER ROUNDTABLE MEMBER ORGANIZATIONS

Founding Organizations:

American Cancer Society
Centers for Disease Control and Prevention

NCCRT Members

Agency for Healthcare Research and Quality
Alliance of Community Health Plans
America's Health Insurance Plans
American Academy of Family Physicians
American College of Gastroenterology
American College of Obstetricians and Gynecologists
American College of Preventive Medicine
American College of Radiology
American Gastroenterological Association
American Medical Association
American Medical Women's Association
American Public Health Association
American Society for Gastrointestinal Endoscopy
American Society of Colon and Rectal Surgeons
Association of State and Territorial Health Officials
Boston Medical Center
C3: Colorectal Cancer Coalition
California Colorectal Cancer Coalition (C4)
C5/New York City Department of Health and Mental Hygiene
Center for Colon Cancer Research
Centers for Medicare and Medicaid Services
C-Change
Collaborative Group of the Americas on Inherited Colorectal Cancer
Colon Cancer Alliance
Crohn's and Colitis Foundation of America, Inc.
Digestive Disease National Coalition
Directors of Health Prevention and Education
Eric Davis Foundation
Foundation for Digestive Health and Nutrition
Hadassah, Women's Zionist Organization of America
Harvard Medical School
Hereditary Colon Cancer Association
Intercultural Cancer Council
International Digestive Cancer Alliance
The Jay Monahan Center for Gastrointestinal Health at New York-Presbyterian Hospital/Weill Cornell
Lynn's Bowel Cancer Campaign (UK)
Mayo Clinic
Minnesota Colon and Rectal Foundation
Minnesota Colorectal Cancer Initiative
Morehouse School of Medicine
National Association of Chronic Disease Directors
National Cancer Institute
National Caucus and Center on Black Aged, Inc.
National Colorectal Cancer Research Alliance
National Committee for Quality Assurance
National Governors Association
New York State Department of Health
The Permanente Medical Group, Inc.
Prevent Cancer Foundation
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Executive Summary

Colorectal cancer (CRC) is both the nation's second-leading cause of cancer mortality and one of its most preventable cancers. If adenomatous polyps were removed before they transformed into cancers, starting at age 50 for those at average risk and earlier for those at increased risk, there would be a precipitous drop in the number of new colorectal cancers. If developing CRCs were detected at earlier stages and ages, mortality rates would fall dramatically. The increase in survival would be impressive. This accomplishment could be one of the great medical achievements of the 21st century. The evidence and tools in this guide will help physicians and their office managers increase screening rates to make this achievement a reality.

Even though highly effective methods of CRC screening are available across the country, the current rates of screening, and of complete diagnostic examination that should flow from screening, remain inadequate. Thus, the potential benefits of widespread CRC are unrealized. The American Cancer Society has established the goal of 75 percent of the eligible population screened for CRC by the year 2015. This guide will help us reach that goal.

There are several proven screening methods that reduce mortality. These are presented as practice guidelines in Appendix A, which offers a chart called "Common Sense Recommendations at a Glance," as well as the consensus guidelines of the American Cancer Society, the US Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology, as well as the guidelines of the US Preventive Services Task Force. Practitioners must become aware that their recommendation is the single most influential factor in persuading individuals to be screened for cancer. This evidence has come from multiple studies in multiple locations over several decades, and it is increasingly recognized and understood. The evidence is presented in the section "Essential #1." Since 75 to 90 percent of Americans visited a doctor for a routine checkup within the past two years, there are many opportunities for physicians to reach the target population with the screening message.

While nearly all physicians screen for CRC, few would claim that every eligible patient leaves the office with the screening recommendation. Only a systematic approach that is designed to identify and provide a recommendation to every eligible patient who visits the practice for any reason is likely to reach the American Cancer Society goal. There are a variety of effective tools to create a systematic approach. The first step is that every practice should have an office policy on CRC screening. This is discussed under "Essential #2." The policy should incorporate an assessment of patient-risk level, and the realities of local medical resources, insurance coverage plans, and patient preferences. Algorithms, flow sheets, and procedures are tools to implement the office policy. They help ensure that it remains consistent into the future. Instructions on how to create an office policy and tools to implement it are presented under "Essential #2."

Reminder systems are another essential element of effective office practice. There are reminder systems that target physicians and those that target patients. Strong evidence from meta-analyses proves that many reminder options are effective. They are presented under "Essential #3." These options will assist physicians and their office managers in choosing their own strategy and tools to attain a high level of consistency and impact.

Skillful communications also improve the effectiveness of office practice. This is discussed in "Essential #4." Theory-based communications are more effective than generic communications. Tools are available to help clinicians utilize a theory-based approach to identify and improve communication with patients who are at different decision stages with regard to screening. These are presented in "Essential #4." Decision aids are also available, and new tools are under development that will soon facilitate shared decision-making between patient and clinician. Office staff can make a significant contribution to this process.

While there are barriers to increasing screening rates, these barriers are now clearly identified and many of them can be overcome. New evidence that first came to light during the 1990s has not penetrated into all practice settings. Some providers may not be aware that national guidelines have changed. Updated knowledge is needed. The digital rectal exam is no longer a recommended screening strategy for CRC. A single sample stool blood test completed in the office is not sound practice. A single positive stool blood test should never be repeated. Positive screening tests should always be followed by colonoscopy. Other barriers that should be removed are presented in Appendix C.

The only way to raise national CRC screening rates is to institutionalize changes in your practice routines so that every eligible patient receives the screening message. It is not enough to know what needs to be done. It is doing it that makes the difference. The evidence-based tools and strategies in this guide will help move your practice to a higher level of performance.

Checklist for Increased Screening

1. Your Recommendation

For CRC cancer screening _____

For complete diagnostic evaluation when screen is positive _____

2. An Office Policy

Policy characteristics

- Determine individual risk level _____
- Identify local medical resources _____
- Assess insurance coverage _____
- Consider patient preference _____
- Attend to office implementation _____

Algorithm posted _____

Stool blood test flow sheet posted, and excludes in-office tests _____

Steps to implement policy in office _____

3. An Office Reminder System

Options for physicians

- Chart prompts _____
- Audits and feedback _____
- Ticklers and logs _____
- Staff assignment _____

Options for patients

- Education _____
- Cues to action _____
- Posters _____
- Brochures _____
- Reminder postcards _____
- Reminder letters _____
- Reminder calls _____

4. An Effective Communication System

Options for action

- Stage-based communication _____
- Shared decisions, informed decisions, decision aids _____
- Staff involvement _____

Goals of This Guide:

- To inform clinicians and their office managers, who deliver primary care about their opportunity to prevent colorectal cancer with appropriate screening
- To encourage primary care providers to decrease the mortality and morbidity of colorectal cancer (CRC) and other cancers through appropriate screening
- To facilitate efforts of office-based clinicians to reduce disparities by applying screening guidelines on a universal basis to the age-appropriate population
- To improve preventive care in primary care practices through use of the strategies and tools presented in this guide

Introduction

Why screen for colorectal cancer?

- Screening both prevents colorectal cancer (CRC) and reduces mortality.

- New insurance reporting requirements include rates of screening for CRC.
- Malpractice suits involving colorectal cancer are costly.
- Continuing medical education (CME) credit is available for improving screening rates in a practice.

Why this guide?

- Every primary care practice can contribute to raising screening rates.
- This guide highlights the essential elements for improved screening rates.
- This guide will help clinicians overcome barriers to screening.

Introduction

Why screen for colorectal cancer?

- Screening both prevents colorectal cancer and reduces mortality.
- New insurance reporting requirements include your practice's screening rates.
- Malpractice cases involving colorectal cancer are costly.
- Continuing medical education (CME) credit is available for practice improvement activities that focus on improved screening for colorectal cancer.

Screening both prevents colorectal cancer and reduces mortality.

Colorectal cancer (CRC) is both the nation's second leading cause of cancer mortality and one of the most preventable cancers.[7 8 9 10 11] It is second to lung cancer as a cause of cancer deaths and shares with lung cancer the unusual distinction of being a largely preventable disease. However, while a lung cancer begins as a tiny malignancy that grows into a larger tumor, a colorectal cancer begins as an adenomatous polyp that is not malignant and takes a period of five to 15 years to transform. This long period of transformation gives physicians an invaluable window of opportunity to help their patients prevent this cancer.

Two developments in medicine have provided doctors with this opportunity. The first was the elucidation of the natural history of colorectal cancer, which was documented and published in the early 1990s.[12] The second was the development of fiber-optic techniques that permitted the exploration of the body's cavities. Together, these advances have created the potential for a giant leap forward in combating colorectal cancer.

The near elimination of new colorectal cancers and a precipitous fall in mortality could be one of the great medical successes of the early 21st century. If adenomatous polyps could be removed from the colon before they turn into cancers, the corresponding fall in new cases of colorectal cancer would be stunning.[13] Mortality from colorectal cancer would be dramatically reduced. The sizable population that is at increased risk because of a family history of an adenomatous polyp or colorectal cancer would be protected from that risk. There are few opportunities in medicine at this time that are as promising as preventing colorectal cancer.

New insurance reporting requirements include your practice's screening rates.

Many primary care physicians are now required to report their CRC screening rates. This information is available and has been presented to the public. Many insurance companies that reimburse physicians for services require this information of practitioners along with other data reports. The Health Plan Employer Data and Information Set (HEDIS), which is disseminated by the National Committee for Quality Assurance (NCQA), and is required for all employer health plans, includes colorectal cancer screening rates on the standard list of quality measures. Colorectal cancer was added to the HEDIS list in 2003, and reported to the public starting in 2006. All clinicians who accept reimbursement from private insurers that provide employee health coverage are affected.

Malpractice cases involving colorectal cancer are costly.

The inescapable logic that supports timely and thorough screening is also producing a growing number of medical malpractice suits. Successful malpractice suits have ranked CRC among the five leading diseases in dollar value of awards garnered.[14] There are a number of factors that combine to make this cancer an easy target for lawsuits and an important focus for risk management.†

The consequences of a missed opportunity to prevent CRC – or to diagnose it early before it has spread – can be grave and life-threatening and can lead to substantial morbidity. Because public awareness of the consequences of this missed opportunity is growing, it can also lead to substantial legal jeopardy and financial loss. A delay in diagnosis and the mismanagement of diagnostic testing are currently the main complaints made in malpractice cases that involve CRC.

The stage of presentation at which CRC is identified and treated is the most important determinant of long-term survival. Early stage presentation and intervention dramatically increase the likelihood of long-term survival and cure. Late stage presentation reduces survival and leads to a poorer prognosis. The beneficial impact for early stage diagnosis and treatment has important implications for office practice and for the public's reaction to a diagnosis of CRC.

Public awareness of the following facts is expanding. As a result, a delay in diagnosis and the mismanagement of diagnostic testing are the main complaints made in malpractice cases that involve CRC. Previously "failure to diagnose" had been the dominant malpractice complaint, especially where patients presented with symptoms. A newer version of this complaint, "failure to screen," is rising in frequency as a principal accusation, especially for patients at increased risk.

1. *The incidence of CRC is fairly high, with a lifetime risk of developing CRC of approximately 5 to 6 percent. People at increased risk may have a lifetime risk that is two to three times the baseline, or 12 percent to 18 percent or even higher.*
2. *CRCs develop from adenomatous polyps (adenomas) and are preventable if the adenomas are identified and removed before they turn into cancers.*
3. *The lead time required for the identification of an adenoma is long. These dangerous polyps typically reside in the colon for 10 to 15 years until they metamorphose into cancers.*
4. *The technology and facilities that are needed to find the adenomas and remove them are widely dispersed, and clearly accessible for those who have health insurance.*
5. *There is a widespread consensus across medical professional organizations and panels of experts that screening for CRC is strongly recommended. In fact, since Medicare began reimbursing for it, CRC screening has essentially become national policy.*
6. *The consequences of a missed opportunity to prevent CRC – or to diagnose it early before it has spread – are substantial. The impact can be large for patients and physicians.*

The logic of these realities has produced many costly lawsuits. The dollar value of malpractice awards for CRC is an indication of expanded awareness and the personal loss when individuals fail to get screening.

† From presentation of Dr. Ernest Hawk, National Cancer Institute, 2002.

Continuing medical education (CME) credit is available for practice improvements described in this guide.

In 2004, the American Medical Association (AMA) established a policy of offering continuing medical education (CME) credits for physicians who undertake quality improvement projects in their practices. This initiative coincides with programs under way at two specialty boards, the American Board of Family Practice (AAFP) and the American Board of Internal Medicine (ABIM). These programs provide credit toward maintenance of certification for physicians who complete online "practice improvement modules."‡ § While each board has its own modules, the boards are collaborating. Completion of an online practice improvement module of the ABIM generates credit toward maintenance of certification from the ABFM. The mutual reinforcement of these activities by the AMA, ABIM, and ABFM reflects the belief that improved medical practice is a priority.

Why this guide?

- Every primary care practice can contribute to raising cancer screening rates.
- This guide highlights the essential elements for improved screening rates.
- This guide will help clinicians overcome barriers to screening.

Every primary care practice can contribute to raising screening rates.

Every practicing primary care physician can contribute to increasing the national CRC screening rate to reach the goal of 75 percent by 2015 established by the American Cancer Society. A recommendation of a physician is arguably the most powerful influence available to attain this goal. A physician's recommendation to participate in cancer screening is a high-impact health message that will result in a large reduction in the risk of dying from this disease. This fact is evidence-based and extensively documented in the literature. It is widely recognized and summarized in the next section of this guide. However, it remains underappreciated by many practicing physicians.

While nearly all primary care physicians do screen their patients for CRC, few practices have systems in place to ensure that this recommendation is delivered to each and every age-appropriate patient. In other words, it is highly likely that every clinician has seen patients in the past few months who should have received a recommendation for screening but did not receive it, and patients who should have been screened but were not screened. Most physicians realize this. In fact, in a national survey, only 20 percent of primary care physicians thought that as many as 75 percent of their age-eligible patients had been screened.[15]

This manual provides strategies and user-friendly tools so that every primary care clinician and practice can increase the percentage of patients who get the screening message and – most importantly – who actually follow through. It provides a road map and a tool kit that all primary care providers and their office managers can utilize to become part of the solution to the problem of colorectal cancer – and other preventable cancers and diseases. While there is work to be done

† American Medical Association. AMA direct credit for AMA PRA Category 1 Credit. Available at: http://www.ama-assn.org/ama/pub/category/16244.html. Accessed July 27, 2007.
‡ American Board of Internal Medicine. Practice Improvement Module. Available at: www.abim.org/online/pim. Accessed July 17, 2007.
§ American Board of Family Medicine. Part IV—Performance in Practice (PPM). Available at: https://www.theabfm.org/MOC/part4.aspx. Accessed July 27, 2007.

everywhere, different work needs to be done in different communities, as well as in different practices. With the approach described here, every practicing physician can expand his or her impact and contribute to the promising nationwide effort to dramatically reduce the scourge of cancer.

The great potential for physicians to raise screening rates with their recommendation to screen is currently unrealized. Despite the tremendous promise of screening, and the attention to its benefits by national print and broadcast media, screening rates remain low across the country. According to the Behavior Risk Factor Surveillance System of the Centers for Disease Control and Prevention (CDC), in 2006, only 24.2 percent of the nation's population age 50 and over had had a stool blood test within the past two years, and only 57.1 percent had ever had a sigmoidoscopy or colonoscopy. This was both good news and bad news.

It was good news because those numbers had improved. It was bad news because many more people need to be screened to achieve a dramatic reduction in mortality from CRC. We have to go even further to realize the American Cancer Society's goal of 75 percent of the eligible population screened by 2015. While there are some indications that screening rates are rising, only a thoughtful strategy and a concerted effort to bring the numbers up will realize the more ambitious goal that has the greatest potential to save lives.

Efforts to reduce the incidence and mortality of colorectal cancer are also part of the national effort to eliminate health care disparities.[16] African Americans have a disproportionately high incidence of and mortality from CRC.[17] Variability in screening rates and lower use of diagnostic testing contribute to this discrepancy.[18] [19] Inadequate awareness of the importance of CRC screening has been cited as an underlying cause, along with lower rates of health insurance, poor access to care, perceptions of bias, or even racism.[20] Other underserved minority groups also have lower screening rates. Cultural barriers are a factor. A physician's recommendation has been demonstrated to be strongly influential with all ethnic and racial groups. An important element of a solution to health care disparities is assuring that a practitioner's recommendation is issued to every age- and risk-appropriate individual.

This guide highlights the essential elements for improved screening rates.

This guide presents essential elements for raising screening rates. There are four. Each will be reviewed in a separate section. Each section addresses one of the key elements and presents strategies and tools to assist in building that element. Some tools are of recent origin. Most are evidence-based. This guide is intended to facilitate success in establishing the four essential elements: 1) Your Recommendation, 2) An Office Policy, 3) An Office Reminder System, and 4) An Effective Communication System.

1) **Your Recommendation.** The first essential for better screening rates is a recommendation from a physician to every patient who is at risk. A physician's recommendation is the most influential factor. The strong evidence on the importance of a recommendation will be presented.

2) **An Office Policy.** The second essential element is an office policy on colorectal cancer screening. The policy assures consistency over time by clearly articulating the intentions of the practitioner and the practice. The policy must incorporate assessment of individual risk levels and be based on local medical resources and local insurance coverage. All staff of the practice should be familiar with the policy and know how to implement it.

3) **An Office Reminder System.** The third element is an office reminder system. There are reminder systems for patients and for providers. Both types can contribute to better screening rates.

4) **An Effective Communication System.** Though communication is a central part of the relationship between the physician and the patient, it typically occurs according to individual habit and inclination or early professional training without attention to techniques that are based on evidence and have actually been demonstrated to improve effectiveness.

The practice that puts the four essentials in place can maximize its impact on the incidence and mortality of colorectal cancer. This guide offers a "how to" for building these four key elements into the practice. The appendix contains the most recent guidelines on colorectal cancer screening, a summary of the screening practices of primary care physicians, and a more detailed discussion to help overcome barriers to screening. There is a knowledge test in the Appendix so you can test your knowledge before and after reading the guide.

This guide will help you overcome barriers to screening.

Barriers and countervailing forces have made it difficult to achieve improved screening rates. This guide provides solutions. Confusion exists about national guidelines. Out-of-date knowledge and outmoded practices persist. Up-to-date knowledge is often derailed by patient demands, or the absence of defined policies. There is a lack of confidence in the efficacy and acceptability of screening tests. Nonexistent or inadequate health insurance coverage is also a barrier. This guide will help physicians and their office managers develop their own strategies so they can overcome barriers and contribute to the success that is within their collective grasp. A discussion of these barriers is introduced here and further explored in Appendix C.

- **Outdated Knowledge.** Some physicians may not be aware that a family history of adenomatous polyps places a patient at increased risk or that CRC in an older first-degree relative also increases an individual's risk.[22 23 24 25 26 27] Some physicians are still performing an in-office digital rectal exam or a single stool blood test; these are not evidence-based and should not be used for colorectal cancer screening. The recommended procedure is an at-home procedure of collecting samples from two or three (depending on which test is used) consecutive bowel movements. Accepted stool blood tests include guaiac-based tests (gFOBTs) and immunochemical tests (FITs). Many abnormal screenings get inadequate or incomplete follow up. Some physicians are unaware of the significance of a single positive stool test and erroneously believe that such a test may be followed up with another set of stool test cards.[28] Every positive stool blood test should be followed up with colonoscopy.

- **Inconsistent Guidelines.** Many primary care physicians are unclear about the current guidelines and, therefore, continue to utilize outdated approaches to screening that are no longer recommended by national professional organizations. Since guidelines have changed, this is not surprising. Though there appear to be inconsistencies among guidelines, in reality, all major guidelines strongly endorse regular screening.
- **Guideline Changes.** As scientific evidence has accumulated, guidelines have changed, most recently in 2002, 2003, and 2008. Outdated guidelines may still be fixed in the minds of some practitioners. In 1989, the US Preventive Services Task Force (USPSTF) judged there was insufficient evidence to recommend for or against fecal occult blood testing (FOBT) or flexible sigmoidoscopy (FS) screening.[29] By 2002, the USPSTF found evidence that several screening methods were effective in reducing mortality.
  Specific guideline changes addressed:
  – The age to begin screening people at increased risk
  – The digital rectal exam, which is not evidence-based
  – Complete diagnostic exam with colonoscopy whenever there is a positive screen
  – Up-to-date guidelines are found in this guide in Appendix A.

In 2008, the American Cancer Society, the US Multi-Society Task Force on Colorectal Cancer (a consortium representing multiple GI organizations and the American College of Physicians), and the American College of Radiology (ACR) agreed to collaborate on an update of each organization's guidelines. These consensus guidelines were developed through a process of collective deliberation between experts from the three organizations and that completed guideline was reviewed and approved by each organization.These up-to-date guidelines are found in this guide in Appendix A.

- **Confusion about Priorities and Goals.**[30] There are two goals of screening. One is to prevent CRC by removing adenomatous polyps that can turn into CRC. The other is to remove early cancers before they become later stage cancers, which carry worse prognoses. The first of the two goals is the more common achievement. Only about 1 percent of endoscopy screenings find a CRC.
- **Lack of Confidence in Efficacy and Acceptability of Screening Tests.** Despite strong new evidence that supports the efficacy of screening, physicians lack confidence in the efficacy of CRC screening tests. Though gFOBT was for many years the test most commonly recommended and despite strong evidence in its favor, only 24 to 35 percent of primary care physicians believe that FOBT is "very effective" in reducing mortality.[31 32] Furthermore, only 43 to 59 percent believe that FS is "very effective" in reducing mortality, despite the fact that evidence has demonstrated that FOBT plus FS can detect significant neoplastic growths in the colon 76 percent of the time and, with appropriate intervention, can reduce mortality by more than 40 percent.[33 34 35] Some physicians may believe that flexible sigmoidoscopy or colonoscopy are distasteful or unacceptable choices for their patients, though there is little evidence to support this. One statewide survey has documented that less than 5 percent of respondents find the nature of the tests inhibiting.[36] News coverage of emerging technologies may also undercut current efforts to increase screening. Some patients and providers may have been waiting until these new, "better" screening methods were available – not realizing how unanimous are recommendations in favor of screening. The

excuse of waiting for new technologies will be largely neutralized by the addition of these methods in the menu of screening options in the 2008 multiorganization consensus guidelines (Appendix A).

- **Cost, Reimbursement, and Insurance.** In one study of physician attitudes, cost was the most common explanation for not recommending colonoscopy (CS.)[37] However, reimbursement has declined and so has cost. Thus, cost could be less of an issue than it was previously. While some private insurers won't pay for every recommended screening modality, most insurance pays for some recommended modality. For example, most insurance will support screening stool blood test followed by diagnostic colonoscopy, if the result is positive. Medicare pays for all screening options except CT colonography and stool DNA testing, which were only recently added to the screening recommendations of major organizations. Absence of health insurance is a more serious problem. The number of individuals nationwide who lack health insurance has risen steadily in recent years. Lack of health insurance is a barrier to receipt of primary medical care and preventive screening services. While a stool blood test is inexpensive and may not require health insurance, the visit to obtain the test will be more costly.** Pharmacies provide stool blood tests in some areas of the country. The colonoscopy, which follows if the screen is positive, may be unaffordable. However, public health authorities may be able to assist in these cases.
- **Inadequate Resources and Reinforcement.** The options for screening in any given community depend on the medical resources in that community and the policies of the dominant health insurers.†† ‡‡ Several states have laws that require insurance reimbursement for colorectal cancer screening. The majority do not. Some states have a high density of specialty physicians, especially gastroenterologists, who perform endoscopic screening. The majority do not. In some areas of the country, medical resources are adequate. In others, they are not.

However, the capacity of the nation to perform CRC screening is not a barrier. There is sufficient capacity to screen the entire unscreened population within one year, using a combination of fecal occult blood testing and diagnostic colonoscopy for positive tests.[38]

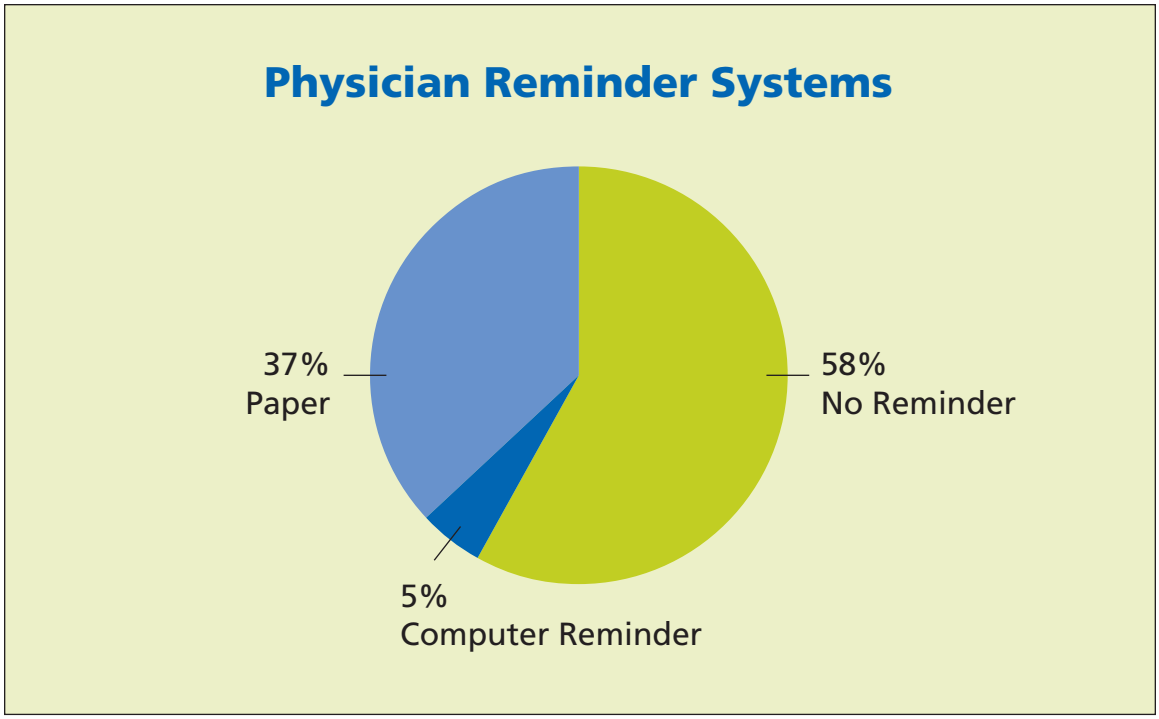
A larger concern is that office practices appear to make limited use of reminder systems. A Wisconsin survey revealed that only 5 percent of primary care physicians had a computer reminder system; 37 percent had a paper reminder system; 58 percent had no reminder system at all.[39]

All barriers and obstacles must be identified, confronted, and removed in order to reap the potential benefits of screening. Achieving a higher standard of office practice by assuring that a screening recommendation goes to every age-appropriate or at-risk patient will start the ball rolling. This guide is specifically intended to help improve the effectiveness of office practice. The material presented here is relevant to all cancer screening and preventive services that have a strong evidence base. The key essential elements described in the guide will not require investment of additional monetary resources, but will require changes in practice routines. These essentials, if implemented, will save time and save lives.

** Unless specified, all mention of stool blood test in this guide refers to either guaiac-based (FOBT) tests or immunochemical (FIT) tests.

†† Medicare issued a new policy in 2001. It began paying for screening CS every 10 years. No longer are symptoms of CRC required in order for Medicare to reimburse for CRC screening with colonoscopy. In 1998, Medicare began paying for annual gFOBT and flexible sigmoidoscopy (FS) every four years and expanded coverage to include annual FIT in 2004.

‡‡ Forty-eight states require that insurers reimburse for mammography screening, but only 20 require reimbursement for guideline-based CRC screening.


Physician Reminder Systems
37%
Paper
58%
No Reminder
5%
Computer Reminder

Four Essentials for Improved Screening Rates

1. Your Recommendation

2. An Office Policy

A. An Office Policy Is Vital

B. Fit the Policy to Your Practice

- Determine Individual Risk Level
- Identify Local Medical Resources
- Assess Insurance Coverage
- Consider Patient Preference
- Attend to Office Implementation

3. An Office Reminder System

A. Options for Patients: Education and Cues to Action

B. Options for Physicians

- Chart Prompts
- Audits and Feedback
- Ticklers and Logs
- Staff Assignments

4. An Effective Communication System

A. Options for Action

- Stage-based Communication
- Shared Decisions, Informed Decisions, Decision Aids
- Staff Involvement

Essential #1: Your Recommendation

1. The positive impact of advice from a doctor to get cancer screening is well-documented.

2. The magnitude of a clinician's impact is considerable: State surveys have shown that 90 percent of people who reported a physician recommendation for CRC testing were screened vs. 17 percent of those who reported no provider recommendation, and 72 percent of those whose physician recommended a stool blood test completed it vs. 8 percent of those whose physician had not.

3. Every clinician has seen patients who should have received, but did not receive, cancer screening. A consistent and reliable recommendation will result if three other essential elements – an office policy, a reminder system, an effective communication system – are part of the practice.

4. The positive effect of a doctor's advice is limited to those who have access to a doctor or a usual source of care. All patients need a usual source of care.

5. To prevent CRC and reduce mortality, the recommendation must include a referral for colonoscopy where any non-colonoscopy screening test is positive.

Essential #1: Your Recommendation

Patients do things their physicians recommend.
They don't do things their physicians do not recommend.[40]

One fact that has remained consistent from community to community is the influence of a physician's recommendation on the cancer screening decisions of their patients. This is an evidence-based finding that has been well-established. Confirmations accumulated over two decades show that a recommendation from a doctor is the most powerful single factor in a patient's decision about whether to obtain cancer screening. While other factors also have impact (including health beliefs, social influences, insurance, and access to care), for those who have a doctor, the doctor's advice is the single most persuasive factor.

The positive impact of a doctor's advice has been demonstrated in studies of cancer screening behavior for several cancers, specifically colorectal cancer, breast cancer, and cervical cancer. The impact of a physician's recommendation was first demonstrated in research on breast and cervical cancer. A physician's recommendation to a woman has been found to be the single most important motivator for mammography and for Pap smear screening.[41 42 43 44 45 46] In fact, lack of a doctor's recommendation is actually experienced as a barrier to screening.

Recent studies have also documented the impact of a doctor's recommendation on screening for colorectal cancer.[48 49 50 51] For older adults, lack of recommendation from a physician is a significant reason for not having a CRC screening test.[52] Having seen a physician within the prior year is one of the strongest predictors of receipt of CRC screening.[53] Having ever received a doctor's recommendation for a flexible sigmoidoscopy makes it more likely that an individual will be screened for CRC.[54] Receiving stool blood test cards from a doctor increases the likelihood that an individual will be screened for CRC. More preventive health visits also increase the likelihood of screening.[55]

STATE SURVEY EVIDENCE

In one state telephone survey of people age 50 years and older, 90 percent of those who reported that their health provider recommended testing had been screened for CRC, compared to only 17 percent of those who reported that they had not received this recommendation.[56] And 71 percent of those whose provider recommended testing thought screening was important, compared to only 48 percent of those who had not received a recommendation.

In another statewide survey in a second state, 67 percent of the population who reported that they received a recommendation from their physician for CRC screening had completed stool blood test in the prior year, compared to 5 percent of those who reported they received no recommendation.[57] Similarly, 85 percent of those who reported that they received a recommendation for CRC screening by endoscopy completed it, compared to 25 percent of those who reported they received no such recommendation.[58]

When those who had not had a flexible sigmoidoscopy or a colonoscopy in the prior five years were asked why, the most frequent explanation chosen (23 percent) was that the "doctor didn't order it or didn't say they needed it." Other reasons included that they had "never thought about it or didn't know they needed it" or that they didn't have any problems. When those who had not had a stool blood test in the prior year were asked why, the most frequent explanation chosen (29 percent) was that the "doctor didn't order it or didn't say they needed it." On an earlier Maryland Survey in 2002, only 5 percent of the population selected that the endoscopy was "too painful, unpleasant, or embarrassing" as the reason for not having had a test. Other frequent explanations included that they had "never thought about it or didn't know they needed it" or that "they didn't have any problems."

ALL ELIGIBLE PATIENTS NEED A RECOMMENDATION

While most primary physicians recommend CRC screening to their age- and risk- appropriate patients, few practitioners have a system in place to make sure they recommend it to all of their patients who are eligible. Only a system with reproducible procedures will do this effectively. There are many options. The next sections of this guide provide a roadmap and the tools with which you can create such a system for your practice. It should be kept in mind that, without a functional system in place, even physicians who have been extraordinarily effective in getting their patients screened will find it difficult to sustain, demonstrate, or prove their achievement.

AN OPPORTUNISTIC APPROACH

While many physicians prefer to give recommendations for cancer screening at the time of the annual checkup, this approach will not reach all the patients in the practice who need screening. An alternate approach is to recommend screening at all types of visits. This is generally referred to as an "opportunistic approach" or a "global approach." The opportunistic approach means recommending screening far more frequently. Given the many demands on a practitioner's time, this approach will only work when office systems function automatically to get a recommendation to every appropriate patient – even if the clinician is not immediately involved. One caveat is that the opportunistic approach does not justify conducting a single sample stool blood test in the office as a screening test. This practice of the stool blood test in the office is not effective.[1]

USUAL SOURCE OF CARE AND HEALTH CARE DISPARITIES

The positive effect of a doctor's advice is limited to those who have regular access to a doctor.[59] Having a regular source of care has traditionally been used as an indicator of access to care.[60 61 62 63 64] Disparities associated with race and ethnicity are predictors of a regular source of care.

Using data from the nationally representative 1996 Medical Expenditure Panel Survey (MEPS), analysts from the Agency for Healthcare Research and Quality reported the racial breakdown of those with no usual source of care as follows: 29.6 percent of Hispanics, 20.2 percent of Blacks, 20.7 percent of Asians, and 15.2 percent of Whites.[65] Consistent with this finding, Hispanic and non-White minorities are the most likely not to receive preventive services.[66] The importance of a regular source of care was more recently underscored by findings from the 2001 California Health Interview Survey. Among interviewees with private health insurance coverage, 53 percent with a regular source of care had had CRC testing, compared to 23 percent of similarly insured individuals with no regular place of care.[67]

Health insurance is also predictive of CRC screening status. Data from the 2002-03 Health Information National Trends Survey, administered by the National Cancer Institute, showed that the uninsured were 64 percent less likely to receive CRC screening than the insured. Uninsured individuals who lacked a provider recommendation were 98.5 percent less likely to be screened.[68] Income is documented as another significant factor.[69]

ADDRESSING DISPARITIES

The problem of health care disparities extends beyond the absence of a usual source of care or health insurance. Black and Hispanic women have been less likely to report having received a recommendation by their physician to get a mammogram.[79 80] Certain people are also less likely to get a doctor's recommendation for screening, especially those people with less education and income – or older age.[81] Demographic factors, such as race, income level, education and age, have been found to influence the amount of time physicians spend in communication with their patients.[82] It comes as no surprise that minority race, limited education, and low family income are related to poor indices of health.

Disparities in the incidence and mortality from CRC are evident. But when recommendations are offered and access barriers removed, screening rates for those with less education and income rise substantially.[75 76] Even though cost should not be a major barrier to screening with stool blood testing because a stool blood test costs little and is not difficult to perform, only testing that is backed up by diagnostic colonoscopy will prevent CRC and reduce mortality.[77]

Fecal occult blood testing on an annual basis, backed up by diagnostic colonoscopy, has sufficient sensitivity to reduce CRC mortality by one-third over 13 years.[78] Access to colonoscopy may be difficult and requires a source of medical specialty services and medical insurance. More efforts are needed to expand access, raise insurance rates, and secure the full range of screening options for the entire eligible population. In 2007, legislation was introduced into Congress (HR 1738) that would create a national system of subsidized colorectal screening programs at the state and local level for low-income, uninsured individuals. If this legislation should pass, access to colonoscopy will improve.

COMPLETE DIAGNOSTIC EVALUATION

Many patients who have been tested and have screened positive fail to get a recommendation for the colonoscopy that should be performed subsequently.[79] [80] Even those who get the recommendation may not complete the evaluation. In 1993, only 38 percent of those who contacted their physician after a positive FOBT received a recommendation for a complete diagnostic evaluation in a health maintenance organization.[81] While recent studies in a similar setting demonstrate that a larger percent (as many as 60 percent) are now likely to get the recommendation for a work-up, the majority may fail to complete the workup.[82] When patients lack health insurance, this problem is undoubtedly worse.

One positive stool blood test should always be enough reason to refer for a complete diagnostic examination with colonoscopy. **A positive stool blood test should not be repeated.** The lack of dietary compliance is no exception to this rule. Similarly, one adenomatous polyp or polyp that was not biopsied on flexible sigmoidoscopy (FS) or polyps seen on barium enema or CT colonography should always be enough reason to refer for a complete diagnostic evaluation. Follow up of a positive screen with a colonoscopy is a risk management issue and is also an important measure of quality of care.

A systematic approach that ensures a colonoscopy for patients who have positive findings on any non-colonoscopy screening test is imperative. Tools have been developed and tested for the purpose of ensuring follow-through. One tool is presented on the next page. It is a template for a systematic approach. The checklist approach has been found useful in improving the quality of practice.[83]

Follow-through rates can be calculated easily by summing the results from the individual sheets. The sheets may be placed on the individual charts and stored in a pending file for CRC screening. The calculation of rates may be utilized as the basis for providing feedback and tracking improvement. This type of assessment may also be achieved by using electronic medical records.

Checklist for Follow Through: From Screening to Complete Diagnostic Evaluation[§§]

gFOBT/FIT Screening	date	FS, DCBE, CTC, or CS Screening (circle one)	date
1. gFOBT/FIT given	_____	1. FS/DCBE/CTC/CS ordered (circle)	_____
2. Provider notified re: gFOBT/FIT result	_____	2. FS/DCBE/CTC/CS scheduled	_____
3. Non-responder contacted	_____	3. No-show identified	_____
4. If gFOBT/FIT +, referral given	_____	4. Rescheduled	_____
5. Colonoscopy scheduled	_____	5. Results reviewed	_____
6. Show/No-show	_____	6. Results on chart for endoscopy/pathology	_____
7. No-show rescheduled	_____	7. If FS/DCBE/CTC +, referral for colonoscopy	_____
8. Results reviewed	_____	8. Show/No-show	_____
9. Results on chart	_____	9. No-show rescheduled	_____
		10. Results reviewed for endoscopy/pathology	_____
		11. Results on chart	_____

Source: RE Myers

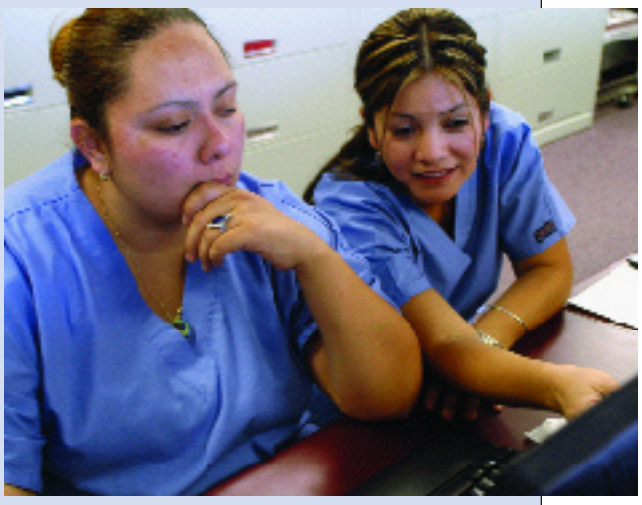
§§ Abbreviations used in this checklist include gFOBT for fecal occult blood test, FIT for immunochemical-based fecal occult blood test, CTC for computerized tomographic colonography, DCBE for double contract barium enema, FS for flexible sigmoidoscopy, and CS for colonoscopy. Stool blood test screening should be done at home with two samples taken from each of two or three consecutive stools (depending on the type of test used). All discussion of stool blood tests in this guide refers to either guaiac-based tests or immunochemical tests.

Essential #2: An Office Policy

A. An Office Policy Is Vital

B. Fit the Policy to Your Practice

- Determine Individual Risk Level
- Identify Local Medical Resources
- Assess Insurance Coverage
- Consider Patient Preference
- Attend to Office Implementation



Essential #2: An Office Policy

> ***"Almost all primary care physicians recommend screening for CRC. Few have systems in place to assure that all eligible patients get the recommendation."*** ***
>
> ***– Richard Wender, MD, 2003***

A. An Office Policy Is Vital

A physician's recommendation is the most consistently influential determinant of a patient's decision to be screened for colorectal cancer. Clinicians should feel confident about this consequential and comforting reality, but it will require more than confidence to ensure that all eligible patients leave their visit with the vital recommendation for screening. Only a systematic approach will achieve this goal.

Office policies are the foundation of a systematic approach. They are the precondition for a reliable and predictable office practice. Effective office practices are built on clear policies, well-designed systems, effective communications, and quality reviews. These pillars of effectual practice do not have to be identically constructed in every practice, but they should be present in some form.

B. Fit the Policy to Your Practice

Your office policy on screening for colorectal cancer must be constructed to address different risk levels. It must also incorporate the realities of local medical practice, insurance coverage, and patient preference. It must be understood and implemented by the office staff.

Since national screening guidelines offer a menu of options, there is room for every physician to design a practice policy that fits the practice. The following should be considered in constructing the policy:

- Individual risk level
- Local medical resources
- Insurance coverage
- Patient preference

While office policy should adhere to national guidelines, it must be appropriate to a specific setting. Every practice exists in a local milieu where there are definable medical resources and standards of care. Preferences and trends also vary from community to community. The screening policy must reflect local resources, standards, and trends. No single policy will fit all practices.

*** Richard Wender, MD, FAAFP, is Chair of the Professional Practices Task Force of the National Colorectal Cancer Roundtable and past President of the American Cancer Society

All national guidelines offer more than one screening option, and nearly all areas of the United States have more than one modality available. This surfeit of options creates a complexity that may actually be a barrier to screening. Some may feel that the existence of options reflects a lack of hard evidence on screening. This is not the case. Thus, a policy on CRC screening is even more important.

While many providers are somewhat confused by the options, their patients are likely to be more confused. All practices should reduce this confusion with a screening policy to strengthen resolve and create the basis for rational office management. A policy may also help address unrecognized and unintended disparities in office practice. Only "not screening is not an option."

Individual Risk Based on Family History of CRC‡‡‡

Familial Setting	Approximate Lifetime Risk of Colon Cancer
No history of colorectal cancer or adenoma (General population in the United States)	6%
One second- or third-degree relative with CRC	About a 1.5-fold increase
One first-degree relative with an adenomatous polyp	About a 2-fold increase
One first-degree relative with colon cancer*	2-to-3-fold increase
Two second-degree relatives with colon cancer	About a 2-to-3-fold increase
Two first-degree relatives with colon cancer*	3-to-4-fold increase
First-degree relative with CRC diagnosed at < 50 years	3-to-4-fold increase

* First-degree relatives include parents, siblings, and children.
Second-degree relatives include grandparents, aunts, and uncles.
Third-degree relatives include great-grandparents and cousins.

††† Adapted from Winawer SJ, et.al., 2003.

Determine Individual Risk Level

An office policy must provide guidance on handling patients at differing levels of risk. In fact, risk stratification is the first step when a clinician considers screening options for any specific patient. (See Appendix A.) Risk stratification is addressed in all the national screening guidelines and is the essential core of the clinician's assessment leading to sound advice. Refer to the table of individual risk based on family history of CRC to obtain the lifetime odds of developing colorectal cancer.

The generally acknowledged risk levels are "average," "increased," or "high," and a specific designation for each individual rests on personal history and family history. Your office policy should specify your recommendation for individuals at "average" risk. Individuals at "increased" risk merit a colonoscopy. Those who are at "high" risk, which is a restricted but frequently missed category, need frequent surveillance starting with early referral for specialized care.

It is preferable for risk assessment to occur at the time of initial entry to the practice and become part of the chart. The sooner risk status is recorded in the chart, the sooner it is accessible to the practice. It should be remembered that, since risk changes over time, an assessment should be repeated with regularity.[86] Annual risk assessment is a workable approach.

AVERAGE RISK

An average-risk individual has no first-degree relatives with a history of either colorectal cancer or adenomatous polyps and has not experienced these problems personally. The average-risk adult age 50 and over has several recommended options for screening.‡‡‡ He or she may be encouraged to utilize any of the options available in the community. The screening options presented in the 2008 joint American Cancer Society/US Multi-Society Task Force/American College of Radiology (ACS/USMSTF/ACR) guidelines include:

Tests That Detect Adenomatous Polyps and Cancer

- Flexible sigmoidoscopy (FS) every 5 years, or
- Colonoscopy (CS) every 10 years, or
- Double-contrast barium enema (DCBE) every 5 years, or
- CT colonography (CTC) every 5 years

Tests That Primarily Detect Cancer

- Annual guaiac-based fecal occult blood test (gFOBT)§§§ with high test sensitivity for cancer, or
- Annual fecal immunochemical test (FIT)§§§ with high test sensitivity for cancer, or
- Stool DNA test (sDNA), with high sensitivity for cancer, interval uncertain

‡‡‡ See Appendix A for current screening guidelines.
§§§ The multiple stool take-home test should be used. One test done by the doctor in the office is not adequate for testing

The ACS/USMSTF/ACR expert panel also strongly encouraged that *colon cancer prevention* be the primary goal of CRC screening and recommended that, to this end, structural exams that are designed to detect both early cancer and adenomatous polyps should be the preferred approach to screening if resources are available and patients are willing to undergo an invasive test.

Informed decision-making should characterize the choice of screening option. Of course, patients cannot make informed decisions unless they have been informed. Shared decision-making, carried out by patient and clinician together, is especially worthwhile and is preferred by many patients. In general, patients are guided by the option their doctors recommend. But, in reality, patient preference is the final arbiter of the available options. Information can help the patient pick the option that confers the best odds of prevention.

INCREASED RISK

An individual at increased risk has a personal or family history of colorectal cancer or adenomatous polyps but does not have one of the high-risk familial syndromes. The individual who is at increased risk doesn't need, and is generally not given, options. This individual should be encouraged to have a colonoscopy. This situation is not rare. A significant percentage of the general population (18 to 20 percent) is at increased risk. Increased risk is common because age is a defining risk factor for CRC and the prevalence of adenomatous polyps rises as people get older. It is 20 to 25 percent by age 50, and 50 percent by age 75 to 80.[87 88] While only a limited percentage of adenomatous polyps turn into cancers, these polyps are the precursors of colorectal cancers.

Both personal history and family history are deciding factors in the determination of risk status. Increased risk may be caused by a personal history of adenomatous polyps or colorectal cancer, or a family history of adenomatous polyps or colorectal cancer. A family history of adenomas or CRC under age 50 should lead to suspicion of a high-risk situation and further evaluation. The individual with a personal history of CRC or adenomatous polyps requires regular surveillance, not screening. Surveillance recommendations for such individuals were recently updated (Appendix A).

The risk factor of a family history of adenoma is frequently overlooked. More attention needs to be given to this risk factor. A family history of an adenomatous polyp in a first-degree relative under age 60 should lead to screening starting at age 40 or earlier. (See the chart "Common Sense Recommendations at a Glance" in Appendix A.) A family history of a polyp of unknown type should be managed as if it were an adenoma. Another factor of personal history that can raise the risk level is a personal history of chronic inflammatory bowel disease (ulcerative colitis or Crohn's disease). Risk is regarded as increased when there is a personal history of these diseases for more than eight years.

Individuals at increased risk should begin screening earlier (age 40 or younger), be screened more frequently, and use the most sensitive screening modality available. At this time, colonoscopy is both the most sensitive and the most specific screening modality available. It is worth remembering that only the absence of risk factors confers a state of average risk. New evidence regarding the most common location for adenomatous polyps has raised questions about an imperative for colonoscopy screening in populations that have a tendency to exhibit polyps in the proximal colon.

HIGH RISK

High-risk patients are those with hereditary colorectal cancer syndromes. These individuals need specialty attention, and they need it early in life. CRC can be prevented in most cases with proper syndrome recognition. The three hereditary syndromes are hereditary nonpolyposis colorectal cancer (HNPCC), familial adenomatous polyposis (FAP), and attenuated FAP (AFAP).

Hereditary colorectal cancer syndromes are under-diagnosed. Identifying individuals at risk for these syndromes is important because their cancer risk far exceeds that of the general population. Identification of those at high risk can be challenging. A family history of an adenomatous polyp or a colorectal cancer in a relative under age 50 may be an indication of a high-risk hereditary syndrome. So might be a history of two relatives with CRC. Early identification of these syndromes is key so that surveillance may begin in the early 20s, or even in childhood.

Patients with HNPCC have an 80 percent lifetime risk for developing CRC. Colonoscopy surveillance should begin for HNPCC between the ages of 20 and 25 with an interval of one to two years. Patients with FAP often present in childhood with hundreds to thousands of colonic adenomatous polyps. The risk for CRC in these patients is nearly 100 percent if the colon is not removed. Gastric, duodenal, and small bowel polyps also occur, but the risk of cancer is less in these areas. Annual surveillance is recommended for patients at-risk for FAP, beginning at age 10 to 12.

Another form of FAP, called Attenuated FAP (AFAP), is a milder version of the disease. The number of cumulative colon adenomas most often varies between 10 and 100, and the onset of polyps and cancer is later than in FAP. Annual colonoscopy is recommended for patients at risk for AFAP, beginning in the late teens to early 20s.

A personal or family history suggestive of one of these syndromes can be evaluated further by genetic testing. The results of this testing can serve to guide management of both patients and their family members. If a disease-causing mutation is identified in a family, mutation-positive individuals can be offered intensive cancer surveillance or prophylactic surgery. Alternatively, those individuals who do not carry the disease-causing mutation are not at increased risk for cancer and can follow general population screening guidelines.

If you suspect a hereditary colorectal cancer syndrome, you may choose to refer your patient to a center that specializes in cancer genetics. You can locate a cancer genetic counselor in your local area by visiting www.nsgc.org. The most common hereditary colorectal cancer syndromes are HNPCC, FAP, and AFAP. Hallmarks of these syndromes include a personal or family history of:

- CRC or adenomas diagnosed prior to age 50
- Endometrial cancer diagnosed prior to age 50
- Two or more HNPCC-related tumors in a family or in an individual[****]
- Multiple colorectal adenomas (usually 10 or more) diagnosed over one or more exams

**** HNPCC-related tumors include colorectal, endometrial, stomach, ovarian, pancreas, ureter and renal pelvis, biliary tract, brain (most often glioblastoma), small bowel, pancreatic, sebaceous gland adenomas and keratoacanthomas (Umar).

RISK AWARENESS

A patient's awareness of his or her personal risk level is very important. Establishing this awareness is paramount. Since family history is so relevant, awareness of the health status of family members is needed and should be encouraged. The first-degree family members of patients who are discovered to be at increased risk are faced with the reality of a change in their risk status. It is advisable to give impetus to a chain of communication so that related family members will learn that their risk level has been altered.

The clinician or staff should instruct the patient to notify his or her first-degree relatives, and this instruction should be documented in the chart. A model letter can be provided to the patient by the practice to facilitate the notification process.

Standardized questions that assist in the determination are found below. When risk level is assessed, the patient should be informed, and notation should be made in the chart. A standard mechanism for determining risk level and making the patient aware of it should be part of the office policy and operating procedure.

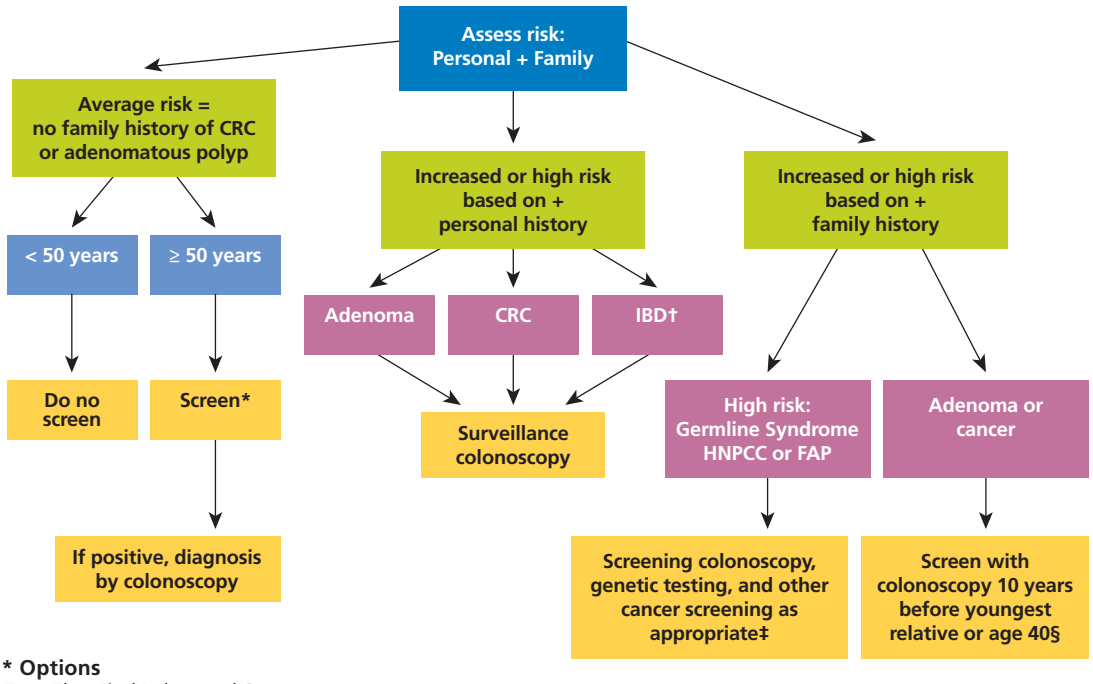
Questions to Determine Risk

- Have you or any members of your family had colorectal cancer?
- Have you or any members of your family had an adenomatous polyp?
- Has any member of your family had a CRC or adenomatous polyp when they were under the age of 50? (If yes, consider a hereditary syndrome.)
- Do you have a history of Crohn's disease or ulcerative colitis (more than eight years)?
- Do you or any members of your family have a history of cancer of the endometrium, small bowel, ureter, or renal pelvis? (If yes, consider hereditary non-polyposis colorectal cancer (HNPCC). Check the criteria.)

UTILIZE AN ALGORITHM

A policy that incorporates the considerations of risk level, insurance coverage, local medical resources, and patient preference will lead to the best screening choice for each patient. An algorithm that incorporates these considerations will be the easiest way to conceptualize and remember the office policy. It may also be the easiest way to communicate the policy to the office staff who will help implement the policy. Refer to the sample algorithm that accompanies this description.

Sample Screening Algorithm



*** Options**

Tests That Find Polyps and Cancer
Flexible sigmoidoscopy every 5 years, or
Colonoscopy every 10 years, or
Double-contrast barium enema every 5 years, or
CT colonography (virtual colonoscopy) every 5 years

Tests That Primarily Find Cancer
Yearly fecal occult blood test (gFOBT)*, or
Yearly fecal immunochemical test (FIT)*, or
Stool DNA test (sDNA), interval uncertain

* The multiple stool take-home test should be used. One test done by the doctor in the office is not adequate for testing.

The tests that are designed to find both early cancer and polyps are preferred if these tests are available and the patient is willing to have one of these more invasive tests.

The algorithm shown includes all the recommended options for the average-risk patient and could be a starter policy for your practice. Average-risk patients will generally have at least two options available. In many locations, they will have all options available. Because there are multiple options for the average-risk individual, provider and patient preferences will interact to produce the chosen modality, unless the office policy limits the recommendations for specific reasons. Patients at increased risk should be given a single recommendation only, for colonoscopy.

Identify Local Medical Resources

Local medical resources will determine what options are available to the patients in your community. Every physician should be aware of the medical resources in their community. A suburban area with a physician surplus will call for a different policy than a rural area or inner city area with a shortage of health personnel. Recommendations lacking realism will guarantee failure.

A stool blood test performed at home requires no facilities and no personnel beyond the patient and staff of the office practice. Stool cards can be dispensed in the office and returned by mail. The other choices for screening, either colonoscopy (CS), flexible sigmoidoscopy (FS), CT colonography (CTC), or double-contrast barium enema (DCBE) require specialized training, facilities, and equipment.

A positive screen requires complete diagnostic examination with colonoscopy. A recent analysis of the national capacity for screening conducted by the CDC concluded that there is sufficient capacity to screen the entire eligible population of the nation within one year, using stool blood testing, backed up by colonoscopy for those who screen positive.[92]

LOCAL CAPACITY FOR ENDOSCOPIC AND RADIOLOGIC SCREENING

Access to colonoscopy (CS) varies by region of the country. The capacity for CS depends on the supply of physicians and nurses, the number of facilities, insurance coverage, regulatory requirements, and other factors. The distribution of gastroenterologists, the facilities for their procedures (free-standing vs. hospital-based), and the capacities of both, are variable. A surplus characterizes some regions; shortage characterizes others.

Hospital-based CS is typically more costly than ambulatory CS. With an ample supply of endoscopists and low-cost ambulatory endoscopy suites, CSs are done efficiently at limited cost and high volume. Where there is shortage of endoscopists and low-cost ambulatory facilities, the wait for CS may be long, the inconvenience large, and the cost high.

CS is not the only procedure with variable access. Access to flexible sigmoidoscopy (FS) also varies greatly. FS is performed by primary care physicians, gastroenterologists (GEs), general surgeons, and, in some settings, by nurse-endoscopists, nurse practitioners, and physicians' assistants. FS is

done easily in the procedure room of a typical practice with no assistance from an anesthesiologist. Yet, paradoxically, it is more difficult to get an FS than a CS in many localities. There has been a substantial falloff in office procedures performed by primary care physicians.[93] Financial pressures and a marked drop in reimbursement rates for FS have reduced the incentive to provide this procedure. To complicate matters, patients referred to a gastroenterologist for a flexible sigmoidoscopy may be advised to have a colonoscopy instead because it is the most sensitive procedure. Conflicting recommendations cause confusion, breed lack of confidence, and will deter patients from choosing FS.

Computed tomographic colonography (CTC), sometimes called "virtual colonoscopy," was recently added to the menu of screening options recommended by major medical and public health organizations. CTC is a radiologic imaging examination that uses computed tomography (CT) to acquire images of the entire colon and rectum. Advanced 2-D and 3-D image display techniques are then used by radiologists to look for polyps, cancers or other abnormalities. CTC is an "image-only" test, and patients with polyps of significant size or other abnormalities detected on CTC will require colonoscopy for evaluation and polypectomy. Like colonoscopy, CTC requires a full bowel preparation and restricted diet. In some settings, same-day polypectomy can be offered without the need for additional preparation; however, this requires coordination between medical specialists (radiologists and endoscopists) and facilities (radiology departments and endoscopy suites). If such coordination is not in place, patients will be scheduled for colonoscopy at a future time and will be required to undergo a second bowel prep. Access to CTC is variable across the country, with a higher concentration in major urban areas at the present time. This is in part due to technical requirements and associated costs; specialized CT softwear is required to perform the studies, and radiologists must receive special training if consistent and reliable interpretation of CTC images is to be achieved. In addition, most insurance plans to do not currently pay for screening CT colonography, although 47 states now offer Medicare reimbursement for diagnostic CTC for certain clinical indications (typically limited to patients who have had an incomplete optical colonoscopy).

A double-contrast barium enema (DCBE) is another accepted screening test for CRC. In the past few years, the number of DCBE examinations done for screening has dropped so much that high-quality screening DCBE may now be hard to access in many communities. At present, DCBE remains an option for direct imaging of the entire colon where colonoscopy and CTC resources are limited, or colonoscopy is contraindicated or less likely to be successful (e.g., prior incomplete colonoscopy, prior pelvic surgery, etc.), or based on factors such as personal preference, cost, and the local availability of trained radiologists able to offer a high-quality examination.

The crafting of each office policy must be based on an assessment of the ease of access and quality of the options in the community.

Assess Insurance Coverage

Health insurance coverage for CRC screening is not uniform across all plans, nor are the options affirmed by the guidelines covered by all plans.[94] Even when all the recommended options are covered, deductibles and copays are typical. The deductibles, in particular, are large enough to be prohibitive for some patients.

As of 2008, only 26 states plus the District of Columbia required insurance coverage for all CRC screening options. Nearly half of all states still have no laws that mandate coverage.[95] Furthermore, some health insurance plans called "self-insured" or "self-funded" plans are regulated only by the federal government, not state governments. Thus, even when states have passed these laws, there are many individuals who will not be covered by these consumer protections. Physicians should be aware of the legal milieu for health insurance in their states and the impact on their patients.

Doctors who practice in states without colorectal cancer screening insurance mandates will have insured patients who are forced to pay out-of-pocket for the entire cost of some procedures, and doctors in states with CRC screening mandates still will have patients who do not benefit from the state law. Every physician knows these factors can be a serious impediment to a patient's care. Insurance coverage has been demonstrated to be a predictor of compliance with cancer screening guidelines. The largest source of coverage for seniors, the Medicare program, began reimbursing for colonoscopy performed as a screening procedure in 2001. Before 2001, only diagnostic colonoscopy was covered by Medicare; screening colonoscopy was not. Today, Medicare pays for screening colonoscopy and most other screening options (with the exception of CT colonography and stool DNA testing, which were only recently added to the consensus screening recommendations and as of this writing, are not yet covered by Medicare). Some providers may remain unaware of the current Medicare policy.

While Medicare policy improved, the copay for screening colonoscopy may still prove to be a barrier for some patients. In addition, reimbursement obstacles confront Medicaid patients. Low-income patients on Medicaid are limited in their options because colonoscopy requires specialty care that is hard to access or unavailable for Medicaid patients in many areas. Private endoscopy suites may be unavailable with Medicaid coverage. Fortunately, stool blood cards can be accessed by many patients in many locations, including pharmacies, at a limited and reasonable price.

States with Legislation on Screening for Colorectal and Other Cancers, 2008

Type of Cancer	Require Coverage	Must Offer Coverage	Not a Requirement
Colorectal	26 plus D.C.	3	21
Breast	46 plus D.C.	3	1
Prostate	30 plus D.C.	1	19
Cervical	24 plus D.C.	0	26

* 2006 data
Source: Kaiser Family Foundation / statehealthfacts.org and ACS CAN data tracking

Patients with no insurance coverage are also limited in their options. While stool blood testing should be available at a modest price, the other more expensive options – flexible sigmoidoscopy, colonoscopy, CT colonography, barium enema and stool DNA testing – must also be paid out of pocket. While some individuals will be able to afford this testing, most probably will not. Some areas have public programs that are making CRC screening available through widespread distribution of stool blood tests and attendant diagnostic workup where indicated. Opportunities for such free testing, or testing at nominal cost, are generally announced by the local health department. Some states, such as New York, Maryland, Delaware, and New Jersey, have screening programs in place. Other states have started demonstration programs with help from the CDC. Federal legislation may soon provide additional funding to support state and local screening programs for the uninsured.

Consider Patient Preference

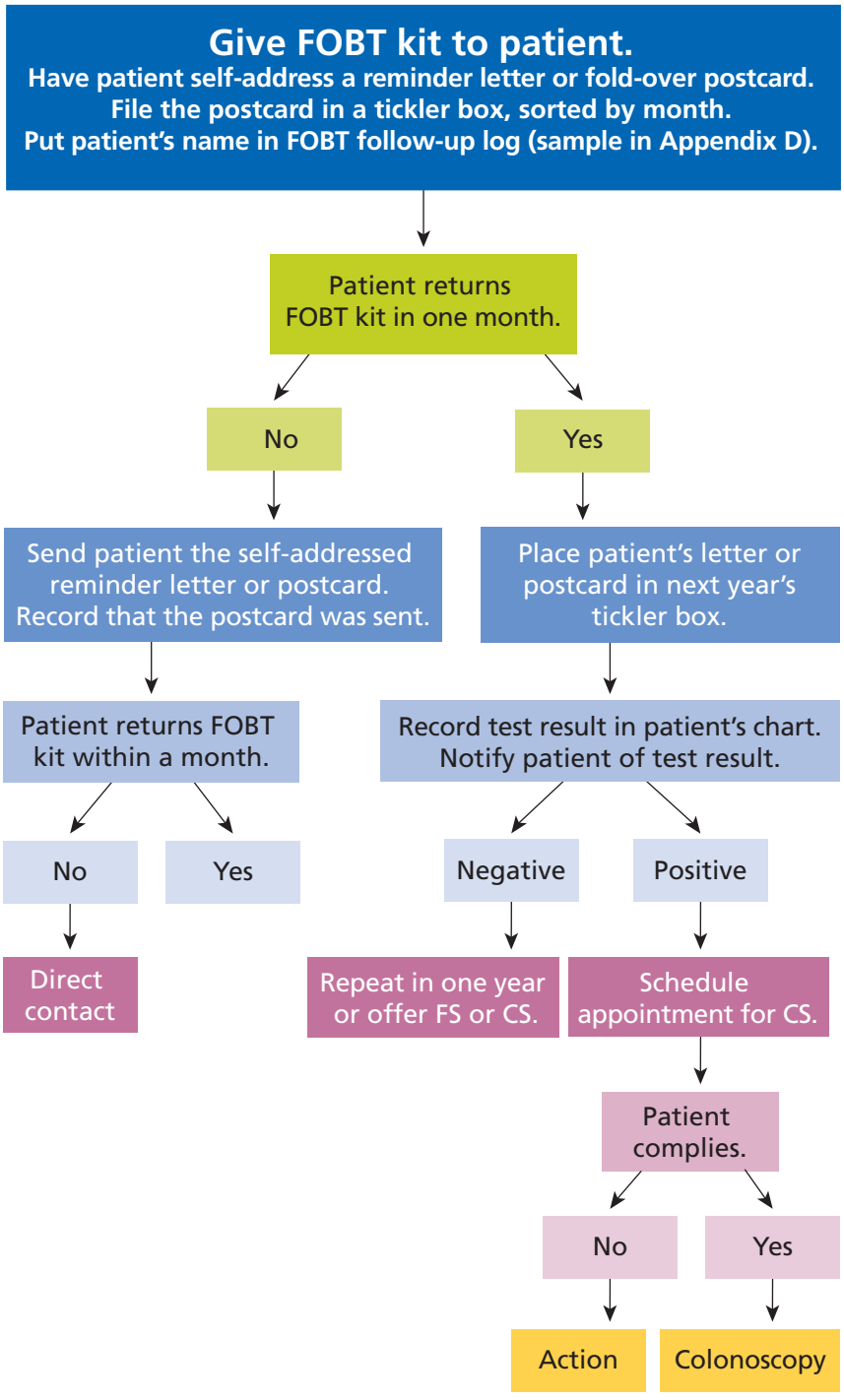
"All of us need to embrace and celebrate every successful screen … The best screen is the one you do."

– Sidney Winawer, MD

The written policy should spell out how the patient will be involved in the decision-making process. It should allow for patient preference within the confines of the realistic options for your locale and the realities of insurance coverage. The simplicity, convenience, privacy, and low cost of a home stool test for occult blood is preferred by some patients, even though it needs to be done annually to reap the benefits. The privacy and relative convenience offered by stool DNA testing may also appeal to some patients; however, the high one-time cost of this test, as well as uncertainty regarding the frequency at which the test should be repeated, may pose barriers to its use. The less frequent, five-year interval and colon visualization offered by a flexible sigmoidoscopy (FS), CT colonography(CTC) and double-contrast barium enema (DCBE) may be more appealing to some, but some of these tests may be difficult to obtain in some regions of the country. Alternatively, the infrequent 10-year interval, and maximal sensitivity and specificity of a screening colonoscopy (CS), has the most appeal to others, but may be difficult to schedule or less available; it also requires a day off from work. The combination of stool blood tests and FS has a higher sensitivity than either test alone and is easily available in some locales. In expert settings, CTC accuracy at detection of cancer and large polyps approaches that of colonoscopy, but geographic and financial barriers may currently limit access to this technology. Another accepted screening option is a double-contrast barium enema every five years, though it is offered infrequently in most settings.

After the pros and cons are presented, a process of shared decision-making involving clinician and patient should revolve around provider advice, local medical resources, and patient health insurance coverage. The provider's guidance on the best choice for each patient should be offered after ascertaining the patient's preferences and/or constraints. The best option is the one that will be completed in each setting for each patient.

Sample FOBT Policy in Flow Chart Form‡‡‡‡



‡‡‡‡ From Seabury J. Tools and Strategies to Increase Colorectal Cancer Screening Rates: A Practical Guide for Health Plans. Harvard Center for Prevention and American Cancer Society, 2004. Approach reprinted from procedures of Dartmouth Medical School, 2003.

Attend to Office Implementation

To actualize an office policy, you must commit to delivering it and engage your staff in the endeavor.[97] Once the policy has been defined, it needs to be depicted, presented, and posted. The office staff must be formally introduced to the policy and have an opportunity to ask questions about its implementation. The presentation of the policy is central to its implementation.[98]

Every practice should have its own screening policy. Though five effective screening options are recommended, the capacity to deliver each varies with the local environment for practice, individual coverage, and state insurance regulations. Given the limitations in personnel and facilities that exist in some communities, you may recommend a scaled-down menu of options or only a single option. Stool blood testing may be the only realistic option, or stool blood testing and colonoscopy may be the only options available. Your practice policy does not need to include the entire menu of options. Even policies that incorporate all options are often presented with a bias toward a particular option. Whatever the policy, it must be disseminated within the office.

The policy on screening should be conveyed in a manner that makes it clear to staff members, old and new. Clarity alone, however, is only half the battle. Staff must know how to implement the policy. Some of the best tools for this purpose are the algorithm and accompanying procedures. An algorithm is one of the sharpest ways to delineate, visualize, and communicate a policy. Step-by-step procedures inform the staff, facilitating its implementation. An algorithm and step-by-step procedures will codify expectations for the provider and office staff. These belong in the manual that holds the policies and procedures for the practice.

Easily accessible reminders can be posted on bulletin boards. They provide a reference point to be revisited when shortcuts threaten to derail the original intentions. Refer to the sample stool blood test policy in this guide in the form of a flow chart or algorithm. This could be posted in your practice.

A sample script can also be helpful to staff.

Sample Script

"I would like you to be screened for CRC. You have a number of choices:"

1) You may choose a structural exam, which is a type of test that is more likely to prevent cancer by finding noncancerous polyps. By removing these polyps we can decrease your chance of developing cancer.
   a) Tests in this category include flexible sigmoidoscopy, double-contrast barium enema, and computerized tomographic colonography, also known as virtual colonoscopy.
   b) Colonoscopy is also a structural exam. You may go directly to colonoscopy for screening. Also be aware that you should always have a colonoscopy if you have an abnormal finding on any of the other screening tests.
2) You can choose a simpler, take-home stool test. These tests are mainly effective at finding cancer early. They may also find some polyps, but are less likely to find polpys and lead to cancer prevention than are the structural exams.
   a) Tests in this category include stool tests that look for blood and stool DNA tests.

Essential #3: An Office Reminder System

A. Options For Patients: Education and Cues to Action

B. Options For Physicians

- Chart Prompts
- Audits and Feedback
- Ticklers and Logs
- Staff Assignments

Essential #3: An Office Reminder System

Reminder systems work.[99] [100] [101] Office practice will be more effective with the use of reminder systems, which are evidence-based and demonstrated to be effective. These systems can be directed at providers or patients or both. Provider-directed and patient-directed systems contribute to improved screening rates.

The evidence for reminders directed at patients is strong. Proven results have come with screening for breast cancer and colorectal cancer.[102] [103] The types of patient reminders and the evidence are discussed below. The evidence for reminder systems directed at providers is also clear. They have been demonstrated to be of benefit in many studies. Several kinds of reminder systems for physicians are presented below. They are not complex. The Appendix (Tools Section) has examples of physician reminders in the form of preventive services schedules, and patient reminders in the form of letters, postcards, and telephone scripts.

A. Options for Patients: Education and Cues to Action

There are two types of patient reminders, those that focus on action, called "cues to action," and those that educate by providing information. Cues to action are straightforward; they are reminder postcards, letters, prescriptions, phone calls, etc. They encourage people to take action. Education, on the other hand, is more complex and can be in two forms, a generic form that presents relevant information in no particular format or theory-based, which uses specific principals and models. The models facilitate consistency in the delivery of health messages that work to help get patients the screening they need.

A meta-analysis of 43 randomized controlled trials on patient reminders of multiple types that were used to encourage women to get breast cancer screening found that most were effective. The degree of improvement in screening rates from the different reminder types ranged from 13-17.6 percent.[104] Many cues to action had impact, but the most effective types were those delivered actively via conversation with a person, either over the telephone or in person. Education that was based on a model or theory was especially effective and far surpassed the effect of generic education.[105]

Cues to action have been shown to be effective with colorectal cancer. Mailed reminders, plus personal phone calls, significantly increased the return of stool blood test cards.[106] Two personal phone calls had more effect than one call. Advance mailing of stool blood test cards with accompanying letters before the appointment increased the rate of CRC screening significantly. The return rate further increased within the full year after the stool blood test card was mailed.[107]

What Strategies Directed at Patients Can Achieve:[89,90]

Office Strategies	Screening Rate Improvement	Comment
Patient education based on a communication theory (i.e., health belief model, stages of change model)	24%	Compared to usual care control group
Cues or office stimuli, like prescriptions, telephone reminders, and letters from clinicians	13%[91]-17.6%[92]	Two options work better than one.
Patient education based on a theory and delivered actively, by telephone or in-person	8%	Compared to active controls*****
Patient education based on a communication theory but not delivered actively	.4%	Compared to active controls
Generic education not based on a communication theory	0%	

Source: Yabroff KR, Mandelblatt JS (1999) (See reference #89) and Legler J, Meissner HI, Coyne C, et. al. (2002) (See reference #90)

Examples of theory-based models of education include the Health Belief Model, Social Cognitive Theory, and Stages of Intention.

***** Active controls receive an alternate and often simpler intervention. Passive controls receive usual care only.

B. Options for Physicians

What Strategies Directed at Providers Can Achieve:[93]	
Strategies	**Screening Rate Improvement*****
Use of "behavioral" innovations like reminders or office system prompts	13.2%
Use of "cognitive" approaches to produce feedback to physicians, such as audits, or providing focused education after assessing knowledge	18.6%
Use of "sociologic" strategies to better use nurses or change staff roles	13.1%
Use of a combination of both cognitive and behavioral approaches	21

Source: Yabroff KR, Mandelblatt JS (1999) (See reference #89) ; Mandelblatt JS, Kanetsky PA (1995) (See reference #95)

All provider-focused intervention strategies have been documented to be effective in raising screening rates.[108] As shown in the accompanying chart, intervention strategies of several types have been studied. They are categorized as interventions of behavioral, cognitive, and sociologic types. All types of interventions have proven effective. They all produce improvements in screening rates. However, the narrower and better focused the efforts, the higher the degree of impact. Interventions focused on both patients and providers have not been more effective than interventions that focused on providers alone. In addition, when combined efforts were used at the community level rather than the practice level, the improvement was minimally successful – only 1 percent.

The evidence is strong that the results of efforts to improve screening rates by focusing efforts on physicians will be worth the effort. Strategies that target the provider all have an excellent chance of succeeding. Decisions on approach should depend on resources, feasibility, and cost. This section will present tools to facilitate implementation of these options.

***** All effect sizes are as compared to usual care controls.

Chart Prompts

Problem lists, screening schedules, integrated summaries, and electronic reminders serve as visual reminders or "cues to action." All clinicians can have their office charts prepared with these elements. Interventions that feature these cues to action have been studied and are found to be effective.

- A problem list on each chart that includes "preventive services" or an equivalent phrase as a separate item is an ongoing cue to action. Patients who are at increased risk for colorectal cancer should have this fact listed as an item on the problem list.[109 110 111]
- Age-appropriate screening schedules should be easy to find on the chart. These are available from professional, governmental, and insurance-based organizations. They can be downloaded electronically. Several are in Appendix D of this guide.
- Some clinicians tout the usefulness of an integrated summary on the front of the chart to provide a complete overview for each patient that includes cancer screening and preventive services. An integrated summary is available online in a version that can be downloaded.[112]
- Electronic medical records can provide integrated summaries and automatic reminders.

Office staff can pull charts ahead of patient visits to identify patients who should be screened. Where screening is indicated or overdue, or the patient is at increased risk, they can use a paper reminder or sticker to flag attention. This adds to efficiency and effectiveness for the provider and has been shown in many studies to improve screening rates.

The same procedures will ensure follow-through for patients who require a complete diagnostic exam with colonoscopy because of a positive screen. Identify the charts of patients who haven't followed through and flag them for action. While chart review in advance of patient visits can increase effectiveness, regular chart audits are a part of quality assurance. Charts that lack documentation of a recommendation for screening, the results of screening, or a colonoscopy (where screening was positive) can be held aside for follow up. The chart review process should generate reminders that can be pursued immediately.

Clearly, it is also important to increase the knowledge base of the clinicians and staff. All staff should understand the importance of screening and be comfortable with the expected office routine and procedures. However, in the final analysis, there is no substitute for a visual prompt – a paper reminder – in the front of the chart to focus provider attention at the right moment.

ELECTRONIC REMINDER SYSTEMS

Information technology systems that are best suited to office practice are still in a period of rapid development. Electronic medical records (EMRs) offer a faster automated version of reminder and follow-up systems and are in active use by clinicians where they are available.[116] Currently, the uptake of EMRs varies greatly around the country – by specialty, region, and practice size. Many office-based practitioners utilize electronic billing and scheduling systems; fewer have electronic medical records (EMR). In the short run, there are electronic tools available for practices that do not yet have full-scale EMRs. One is described in the next section.

Full-scale EMRs will be more and more prevalent over the next decade.[117] [118] The federal government, Medicare-quality organizations, and major professional societies have embarked on programs to help practitioners develop electronic record keeping and management systems. The Veterans Health Administration has made available at low cost its medical record system, which was updated for ambulatory care. The Center for Health Information Technology (CHIT), established by the American Academy of Family Physicians, is currently working with 10 major technology companies to promote and facilitate the use of health information technology by family physicians.†††† In the years to come, there should be more EMR systems that meet the needs of primary care practice and facilitate preventive screening.[119] Their efforts must conform to four principles: affordability, compatibility with prior and other newer systems, interoperability so that data can be shared between systems, and data stewardship to guarantee privacy and proper use of data. Due to the efforts of the CHIT partnership, the price of such systems should be reduced by 15 to 50 percent.[120]

Ratings of existing EMRs that can help guide physicians who are looking for the best version for their practice have appeared in the literature.

A listing of EMR features is available in the journal *Family Practice Management.*[121] There are also evaluations of EMRs – one is available for free online, another is proprietary. The AC Group report established a rating system that included the Institute of Medicine's requirements for a computerized patient record; it is available online.‡‡‡‡ The KLAS report is a proprietary compilation of data gathered from Web sites, health care industry reports, interviews with health care provider executives and managers, and vendor and consultant organizations.§§§§ The existence of a reminder system for preventive services should be a criterion for choosing the EMR. Preexisting EMR systems may have upgrades available to add preventive services and reminders.

†††† The partner companies are A4 Health Systems, GE Healthcare, MedPlexus, MedPlus, NextGen, Physician Micro Systems,Inc., SOAPware, SureScripts, WelchAllyn.

‡‡‡‡ 2004 EMR Survey is a white paper done by the AC Group. www.acgroup.org/pages/396843/index.htm. This is the third annual report on electronic medical records and electronic health record applications.

§§§§ Ambulatory EMR Perception Report. January 2004. KLAS Enterprises. www.healthcomputing.com.

ELECTRONIC TRACKING FOR PREVENTIVE SERVICES

There is also easy-to-install, user-friendly software available at a low cost that can be utilized to track preventive screening services. The Patient Electronic Care System (PECSYS) makes it easy to store and retrieve information and to produce lists of age-eligible patients or patients with specific conditions and patients who have had – or have not had – specific screening tests.[122] The system incorporates automatic reminders. This software is relatively inexpensive. It was developed in conjunction with the community health center program under contract to the Bureau of Primary Care Services in the Health Resources Services Administration of the federal Health and Human Service Department. It may also be used to improve the ease and quality of medical practice. It is especially useful for chronic disease management. It does not currently provide either billing or scheduling capabilities, however.

PECSYS is an improved version of a system that has been in use for several years. It prints out a unique, age-appropriate encounter form for each patient. The encounter can be attached to the chart as the patient comes in. This encounter contains (see page 39) specific information about the patient from prior visits, including summary graphs of key data. It includes reminders in red ink for those preventive tests that are missing. Depending on age, gender, and what diagnoses or conditions have been previously entered for that patient, the appropriate reminders, diagnostic tests, and patient education needs will appear automatically, based on established preprogrammed treatment guidelines.

Another system that operates on similar principles is ClinfoTracker.[123] It will prompt only when appropriate. And it integrates clinician input into the prompting process. It was developed with attention to cognitive issues including the need for physicians to focus, prioritize and avoid distraction.

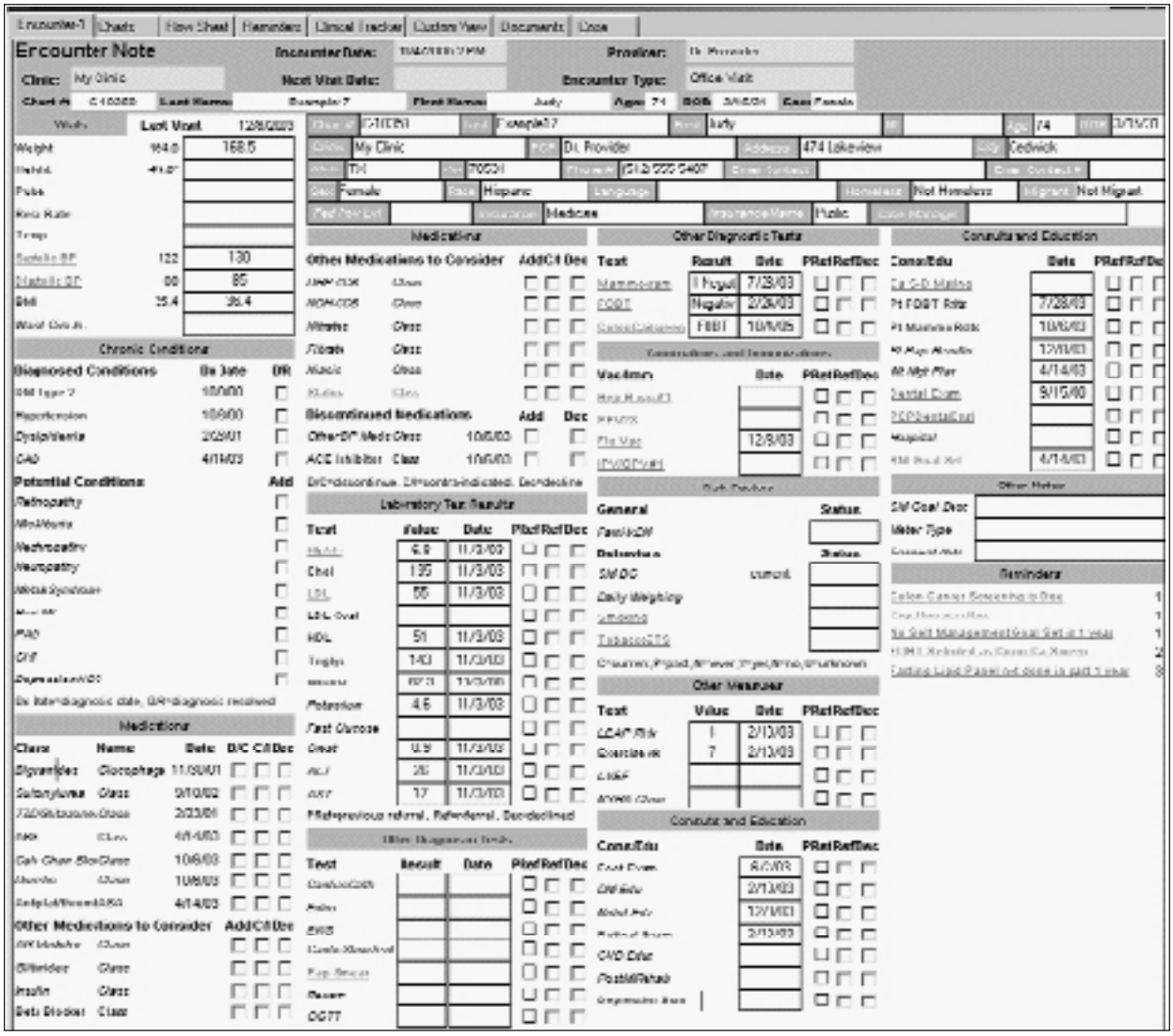
The patient-specific encounter forms of PECSYS and ClinfoTracker already include data from prior visits. PECSYS includes vital signs, diagnoses, medications, lab tests, diagnostic studies, preventive services, immunizations, and referrals for consults and education. It automatically incorporates the last results on one page, so it presents a quick, comprehensive overview. The encounter sheet becomes a flow sheet of high-priority information that would otherwise be time consuming to dig out of the chart. If the office staff prints an encounter for each scheduled patient, this information is available before the encounter begins. For example, the encounter sheet for a man age 50 who has not had CRC screening and who carries the diagnosis of diabetes will have CRC screening appear in red on his encounter sheet. Diabetes-specific lab results like HgbA1c and microalbuminuria will appear on the encounter form in red if they are missing, or they'll appear with the results of the last several tests.

Physicians may type data directly into the system during the patient encounter or write on the encounter form in a space provided for that purpose. The encounter sheet with the physician's current progress note is placed in the chart like any other chart note. While data entries on each patient are necessary to start this system off, data can be entered over a period of time as patients come in – or it can be entered for all charts at once.

Once the initial patient data are entered, data entry is limited to new findings, labs, diagnostic tests, and consults as they are completed or as results come in. The time necessary to enter these into the electronic system is little more than the time that would be needed to place them in the chart. Each new patient visit may then be accompanied by a printout of a fresh encounter form that includes the most recent data. A second page can also be printed out automatically with its graphs of the patient's blood pressure measurements, weight, or key lab values as measured over time.

The PECSYS system can operate on a personal computer or a laptop and in a network. It installs a modified version of Sequel for data storage. While the PECSYS software does not currently interface with scheduling or billing, there are new modules under development that should provide this capability.

Encounter Form from Patient Electronic Care System (PECSYS)



ADVANCE PREPARATION WITH THEORY-BASED QUERIES

With or without electronic reminders, considerable time can be saved if office staff anticipate visits by reviewing the charts before the patient arrives or by querying the patients before the clinician encounter.[124] A brief questionnaire can be provided by the front desk staff, or questions may be added to the office's current list of questions asked by the nurse or medical assistant in the exam room.[125] The questions should determine the patient's risk level and prior screening history.

This information provides an excellent opportunity to define the CRC decision stage of that patient, as described below, so that a theory-based education effort can ensue. As described under the section on patient reminders, theory-based education has been convincingly shown to be effective, whereas generic education has not.[126] This type of approach has been specifically investigated for relevance to CRC screening.[127] [128] This will be explained further under "Essential #4: An Effective Communication System." An advance query with a theory-based approach is both a form of reminder and an example of communication that employs the use of theory-based education.

Decision stages:

- Never heard of CRC screening
- Heard of, but not considering CRC screening
- Heard of and considering CRC screening
- Decided against CRC screening
- Heard of and decided to do CRC screening

Once a patient's decision stage is defined, a patient can be encouraged to make a transition from one stage to the next with a focused pitch. Stages and focused pitches are depicted in the accompanying figure. The stage of decision guides the clinician or staff to make the best use of face time with the patient by speaking directly to the central issues of that stage.

The patient who has "never heard of " colorectal cancer screening needs information about the risk of CRC, the available screening methods, and what screening will accomplish. The patient who has "decided against" screening can be approached with an inquiry about the reasons for the decision. These might then be addressed. The patient who is "not considering" it also needs probing so that his or her lack of inclination to get screened can be understood. The patient who is "considering" screening needs to be questioned for perceived barriers and provided help on following through. The patient who has already "decided to do" screening may need only logistic instruction and/or assistance.

Decision Stages and Corresponding Physician Message

Decision Stage	Physician Message
1. Never heard of CRC screening	1. Provide basic information about risk of CRC and benefits of screening.
↓	
2. Heard of, but not considering CRC screening	2. Remind patient about risk and benefit of CRC screening. Discuss screening options.
↓	
3. Heard of and considering CRC screening	3. Assist patient to select a screening option. Help identify barriers and possible solutions.
↓	
4. Heard of and decided to do CRC screening	4. Discuss logistics. Answer questions.
0. Decided against CRC screening	0. Probe for reasons and address them.

Audits and Feedback

Audits and feedback that provide focused information after assessing knowledge have been referred to as "cognitive" reminders. They can be viewed as tools to measure progress or as a cognitive cue for the clinician. Evidence from meta-analysis indicates that a practice can achieve an 18.6 percent improvement in screening rates by using audits that produce feedback for providers.

The simplest chart audit involves pulling a certain number of charts of the target population and reviewing each chart to document whether certain elements are found on the chart. Chart audits can produce feedback for a specific clinician or an entire practice. However, there is evidence that feedback is more effective if it is specific. After the requisite number of charts have been reviewed, the results in each category are tallied.***** There is a sample chart audit template in the tools section in Appendix D.

While chart reviews are time consuming, collecting this information is not complicated and is essential for maintaining the quality of practice. A context is needed to interpret the results of an audit. The results can be put in perspective through national or local benchmarks. For example, a 75 percent screening rate may not satisfy the provider but it may be above the national average. Comparison helps the clinician understand the results in the context of national trends and goals. Such information is available online from the National Committee for Quality Assurance (www.NCQA.org).

Goals and measures with which to track them have been set by national collaboratives of primary care clinics. The Bureau of Primary Care in the federal Health Resources Services Administration has worked with selected clinic practices to create registries of patients who can be tracked for cancer screening and chronic disease management. The registries facilitate tracking and documentation of practice improvements. The chart that follows lists some of the measures these practices have used for CRC screening.

The time interval for repeat audits depends on the size of the practice, the patient population, the staffing level, and the reminder system that has been created. A baseline audit, a follow up audit, and an additional audit after a year has gone by will provide insight about the effectiveness and endurance of change(s) in the practice. The baseline and follow up will measure whether there have been changes.

Audits will now generate CME credit toward the Physician's Recognition Award as part of an AMA initiative to provide credits for performance improvement activities.[129] This initiative coincides with programs under way at two specialty boards, the American Board of Family Practice (ABFM) and the American Board of Internal Medicine (ABIM). These programs provide credit toward maintenance of certification for physicians who complete online "practice improvement modules" (PIMs).[130 131] These PIMs include web-based data abstraction tools, feedback reports, access to guidelines, and individualized action plans with alternative interventions that may be chosen by the physician.[132] While each board has its own modules, the boards are collaborating. Completion of an online PIM of the ABIM generates credit toward maintenance of certification from the ABFM. The mutual reinforcement of these activities by the AMA, ABIM, and ABFM reflects endorsement of the belief that audits and feedback lead to improved medical practice.

***** A chart audit will pull information from each chart: age, gender, race/ethnicity, and risk status of each patient. It is most useful if it records multiple dates, including when the test or procedure (stool blood test, colonoscopy [(CS)], flexible sigmoidoscopy [(FS)], DCBE) was recommended, when the stool blood tests or referral for procedure was issued, when the results returned, and when the patient was notified. Finally, it may include findings about whether hyperplastic polyps, adenomatous polyps, CRC, or other diagnoses were found. Each category of data is tallied, and results are computed over the appropriate denominator. Physicians who wish to determine the parameters of their own chart review, will find a sample size calculator online at the Web site of a Medicare quality of care contractor, www.cmri-ca.org. This automatically calculates appropriate sample sizes for quality improvement projects.

Measures Used by Collaboratives for Colorectal Cancer

Sample Measures	Definition	Data-gathering Plan	Goal	Notes/ Comments
1. Percent of adults age ≥ 50 who have been screened for colon cancer	1. Number of adults age ≥ 50 who have been screened with at least one of the following: – FOBT/FIT w/in 1 yr – FS w/in 5 yrs – CS w/in 10 yrs – CTC w/in 5 yrs – DCBE w/in 5 yrs divided by the total number of adults ≥ 50. Multiply by 100 to get the percentage.	1. On (date) the registered patient database will be searched for all adults ≤ 50 who have been screened with at least one of the following: – FOBT/FIT w/in 1 yr – FS w/in 5 yrs – CS w/in 10 yrs – CTC w/in 5 yrs – DCBE w/in 5 yrs At the same time, count the total number of adults[3] 50 yrs in the registry or practice.	> 75%	
2. Percent of patients with documented notification of colon cancer screening results on their chart within 30 days	2. The # of adults age ≥ 50 having documented notification of colon cancer screening results on chart within 30 days of test, divided by the total number of adults ≥ 50 having documented colon cancer screening within the past 12 months. Multiply by 100 to get percentage.	2. On (date), the registered patient database will be searched for all adults ≥ 50 having colon cancer screening results on chart.	> 90%	
3. Percent of patients requiring complete diagnostic evaluation (CDE), completing that evaluation within 60 days	3. The number of adults ≥ 50 with + FOBT/FIT or a polyp on FS or polyp on CTC or polyp on DCBE having complete diagnostic evaluation (CDE) documented within 60 days, divided by the total number of adults ≥ 50 with +FOBT/FIT or a polyp on FS or polyp on CTC or polyp on DCBE. Multiply by 100 to get percentage.	3. On (date), the registry will be searched for the number of adults age ≥ 50 with +FOBT/FIT having CDE within 60 days. At the same time, count the # of adults who had a + FOBT/FIT OR on (date) search for the # of adults ≥ 50 with a polyp who had CDE within 60 days of identification.	> 95%	
4. Percent of adults age ≥ 50 with adenomatous polyp or CRC having their initial treatment documented within 90 days of lab confirmation of the diagnosis	4. The # of adults ≥ 50 with adenomatous polyp or CRC having initial treatment documented within 90 days of lab confirmation of the diagnosis, divided by the total number of adults ≥ 50 with adenomatous polyp or CRC. Multiply by 100.	4. On (date), search for the # of adults ≥ 50 with adenomatous polyp or CRC who have their initial treatment documented within 90 days of lab confirmation of the diagnosis. At the same time, count the number of adults ≥ 50 with adenomatous polyp or CRC.	> 95%	

Adapted from: http://healthdisparities.net/Cancer. Measures_Mar05.html, accessed November 2005.

Ticklers and Logs

Other traditional systems to ensure compliance include tickler systems and logs.††††† A tickler system is created when a copy of a lab order, referral, reminder letter, or tracking sheet is placed in a "tickler file." A tickler file is a series of file folders, one for each month of the year. (Sub-folders for each day of each month may be added.) The copy is filed by date of the visit. The contents of each folder are organized alphabetically. When results or reports arrive, the copy is pulled from the tickler file, the patient notified by phone or mail, the results placed on the chart, and a visit scheduled if appropriate.

On a specific day each month, all the copies in the tickler file are reviewed. Orders with no accompanying results should prompt follow up. And the patients in question should receive phone calls, postcards or letters. The tracking sheets placed in the file for a patient are started when he or she begins the screening process. Regular review of tracking sheets in the tickler file will assist the physician or the practice to follow the screening process through to completion including follow up of abnormals. For physicians who wish to apply this system to repeat screenings in the subsequent year, file folders may be created for the next year as well. A reminder letter with the patient's name on it, or a copy of the original result, may be placed in one of the file folders for the subsequent year.

Postcard tickler systems are similar. The patient self-addresses a fold-over reminder and/or result postcard which is used for the tracking of stool blood tests. This is placed in the tickler file by the date of the office visit. If the stool blood test is returned, the fold-over postcard is pulled and the test results sent to the patient and documented in the chart. At the end of the month, the remaining postcards from the preceding two months are pulled from the file. Patients receive their own postcards to remind them to return their stool blood tests. A record should be kept when reminder postcards sent for the purpose of additional follow up.

Another approach to improve patient adherence is to create a single log or tracking sheet of all patients who take home a stool blood test kit. Such a tracking sheet can be found in Appendix D. Many practices keep logs for strep cultures. A stool blood test log is similar. The log can be used to record information and contact patients with the results of the tests. It can also be used for telephone calls or reminder letters for patients whose kits haven't been returned. Patients with positive screens should have a colonoscopy. The log can be used to ensure colonoscopy follow up for these patients. It can also track those screenings that employ flexible sigmoidoscopy or colonoscopy to ensure completion. Logs and tracking sheets are found in Appendix D.

Staff Assignments

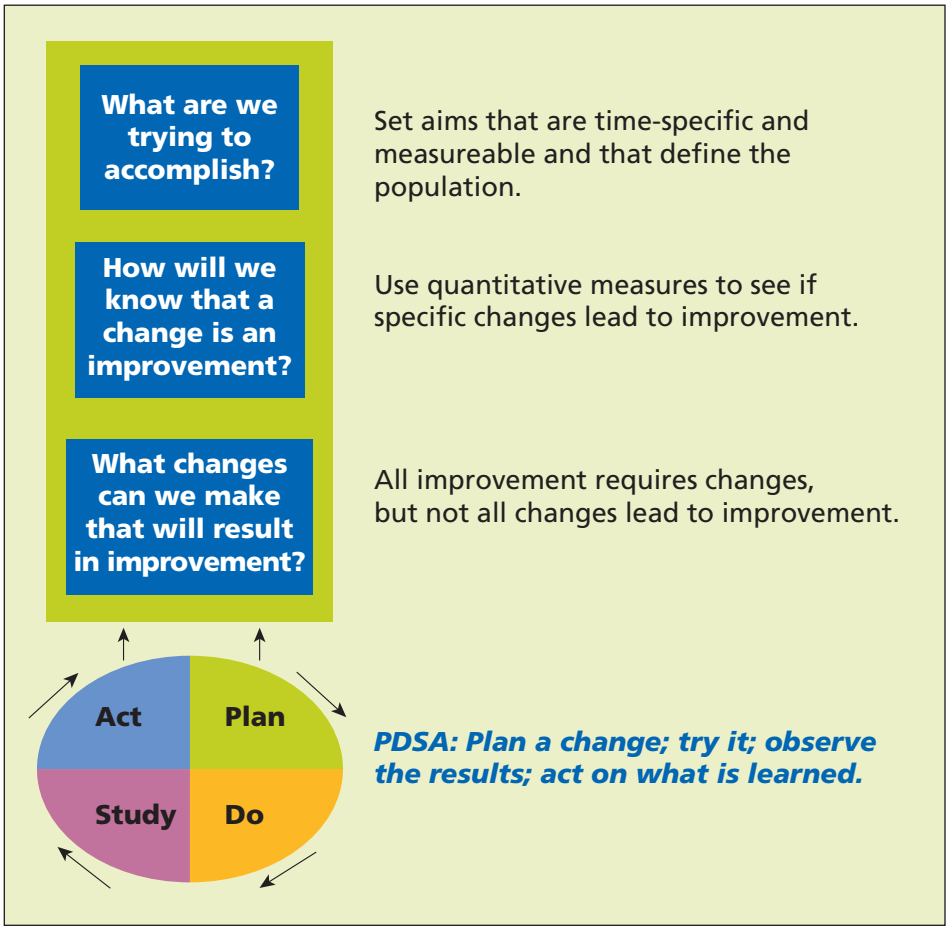
Reminder systems that are not of the paper or telephone type include changes in the practice routines that involve staff and staff responsibilities. Changes in staff routines and staff assignments can increase the ordering of preventive care services. Office procedures are built on human routines and systems that incorporate staff in the office.[133] [134] [135] The effectiveness of your practice can be improved by including different staff in the process of cancer screening by using the same office

††††† This description is from the Harvard Center for Cancer Prevention, 2003.

staff but deploying them differently. The assignment of responsibilities and the flow of patients through the staffing pattern of the office will help or hinder the outcome. Changes in responsibility and flow can be made and evaluated.

Staff can help boost screening rates by encouraging screening or even initiating the process. You can empower them to do this.[136] The changes you make will constitute a reminder system. This section presents two different models for making changes – Model A and Model B. Both have been developed by organizations that promote quality improvement and have provided assistance to federal programs. Both are accessible over the Internet. The first model, presented in a flow diagram, is offered by the Institute for Healthcare Improvement.[137] The second is presented in text form by an organization known as Lumetra.[138]

Model A. This model has two parts. The first part poses three questions that can be asked in any order. One question is in each of the square boxes in the diagram below. The second part is the "Plan-Do-Study-Act (PDSA)" cycle for testing and implementing change. The PDSA cycle helps you test the change to see if it is an improvement or not. A diagram of the model is depicted below.



Source: www.ihi.org/IHI/Topics. accessed May 2004.

Examples of system changes to increase CRC screening rates include:

- Informing patients ahead of time so they are ready to make a decision
- Having staff other than the provider present the options to the patient
- Assessing the patient's decision stage before the provider encounter
- Sending brochures or education materials to the patient before the appointment
- Sending a letter that describes the doctor's recommendation before the visit

Model B. This model is a step-by-step guide to help you establish a reminder system. An organized system is needed in every office to remind patients and providers of the need for CRC screening services. The reminder system can save time and effort, improve health outcomes, and help meet guidelines and regulatory requirements. It can also be the most cost-effective approach.[139] It is important to plan, implement, and follow up on the changes.

1. Plan

A. Evaluate the current system. (See sample chart audit pages in Appendix D.)
B. Include office staff as part of the planning team.
C. Establish shared goals for improving screening rates.
D. Determine new procedures.
E. Assign roles and responsibilities to team members.†††††††

2. Implement

A. Implement the new roles and responsibilities.
B. Meet regularly to identify and solve problems.

3. Follow up

A. Track the changes.

††††††† See reference #118.

These are examples of possible changes to a visit:

1. **While in the waiting room:**
   - The patient may be asked to complete a questionnaire to provide information on risk status, screening history, and attitudes.
   - Place informative and attractive office posters or fliers in the waiting room or exam rooms as an expression of your own policy and as cues to action.
   - Customize the use of educational materials, instructional materials, and reminder tools to suit your practice needs.
2. **At patient check-in:**
   - Have staff ask about preventive care and highlight services that are needed or past due.
   - Use preventive care flow sheets and reminder chart stickers.
3. **During the visit:**
   - Ask patients about family history and previous screening.
   - Let your patients know that getting CRC screening can prevent cancer and save lives.
   - Schedule screening before the patient leaves the office.
4. **At checkout:**
   - Have patients fill out reminder cards. File reminder cards by the month and year of planned notification.
5. **Communication beyond the office:**
   - Contact patients in need of preventive services for the following month.
   - Send patients a stool blood test in the mail in anticipation of a visit.

Tracking patient compliance assures that the changes achieve what is intended. Here are suggestions for techniques:

- On a periodic basis, pull charts of patients in the "screening completed" file to see if results are on the chart.
- Track patient compliance by phone to verify screening or provide a reminder for those who were given a referral. If screening is already done, mark this on the tracking sheet or place a copy of the results in a "screening completed" file.
- Perform ongoing preventive service assessments at the time of the visit and document them.
- Use patient personal health record booklets and encourage all patients to bring their records to every visit.

Essential #4:
An Effective Communication System

A. Options for Action

- Stage-based Communication
- Shared Decisions, Informed Decisions, Decision Aids
- Staff Involvement

Essential #4: An Effective Communication System

There are many arguments in favor of effective and skillful communications. Communication strategies can facilitate and promote the delivery of health messages that work to help get patients the screening they need. Many studies have found that "theory-based" strategies have the largest effect on patient behavior. Though evidence has been published, descriptions of theory-based interventions in the medical literature are more likely to be known to certified health educators than physicians. A meta-analysis of patient education interventions for breast cancer screening revealed that theory-based education strategies were far more effective than generic education strategies. They increased screening rates by 24 percent, compared to generic information, which was no more effective than usual practice.[140] The improvement was greater when the approach was active, involving conversation with another individual, either over-the-phone or in-person.[141]

Skillful communication routines can save time. In many settings, a clinical encounter is shorter than it has ever been, and the pressure on the encounter is greater than it has ever been.[142] Studies confirm what primary care physicians know well: There is less time to do more. This may not seem like the opportune moment for adding items to the agenda for each medical visit. Thus, a communication tool that takes pressure off the clinician while achieving maximum effect will be a valuable asset.

Skillful communications will increase impact. There is substantial evidence that a physician's recommendation is the most effective strategy for persuading individuals to complete cancer screening. If physicians and their staff wish to realize their full potential to promote screening, they will need to get a recommendation to every eligible patient in the most efficient way possible. Communication tools facilitate this process.

In general, effective communication is a cornerstone of good practice. Physicians' communication skills are related to patient satisfaction. Patient satisfaction affects outcome. Studies and reviews in the literature document the benefit of enhanced communication between doctors and patients for the successful management and outcome of the care process.[143] [144] [145]

An informal rating of the doctor's "bedside manner" is probably the most common reference to a doctor's communication skills. However, effective communication not only satisfies a patient's need for skilled verbal interaction, but also builds productive relationships that lead to desired outcomes. One of the outcomes is the completion of preventive services. New research has begun to guide the way to more effective and skillful communication with patients where decision-making is necessary.[146] This research is building on top of evidence accumulated from two decades from research on improving screening rates for breast cancer.[147]

A. Options for Action

Stage-based Communication‡‡‡‡‡

Stage-based communication methods may be the easiest strategy to understand and implement. Tools based on this model have been developed specifically for use in colorectal cancer screening. Based on the work of Prochaska and DiCelemente, stage-based models have been discussed in the medical literature for more than two decades.[148] These methods grew out of efforts to construct a model that would transcend all other communication theories and help patients move through processes of change to achieve desired outcomes.

This approach defines stages of a patient's thinking to guide the provider with precision to the message that the patient needs to hear. The provider's time is then used more wisely. There is no need to repeat what the patient already knows, understands, and is familiar with. According to a leading expert in communication, stage theory allows practitioners to treat individuals "as they are – in different stages of readiness to make health behavior changes."[149] The right information at the right time is the communication that will make a difference.

THE STAGE-BASED MODEL FOR EFFICIENT COMMUNICATIONS

When a patient's stage of readiness is known, the patient can be approached with a sales pitch appropriate to that stage. A patient who has never heard of the issue needs basic information to increase their awareness of colorectal cancer. A patient who has decided to act on screening may only need "how-to" instructions, while a person who is truly undecided about screening will need to be convinced of its value and its acceptability.

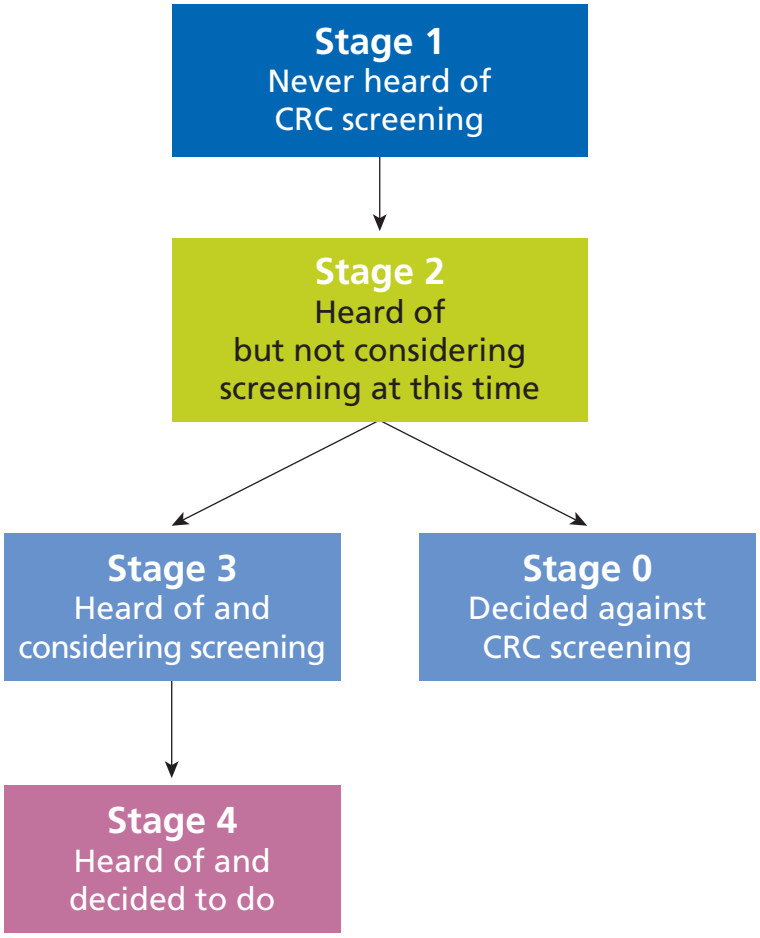
There are several models that utilize stages of readiness as a tool to guide information exchange and conversation. The names of the stages may vary in the different models, but the basic idea remains constant, and provides a framework to assist the clinician and staff in addressing the issue that is most relevant to the individual patient. Simple questions can define the stage of readiness of an individual and guide the clinician or staff to use the most relevant information or argument. Spoken and written communications can be based on this efficient framework. The version of stage-based communication presented here recognizes five "decision" stages.§§§§§ These decision stages are visualized in the figure. This model has been tested for effectiveness with colorectal cancer screening.

There are several approaches to determination of stage. One that has been tested is presented here. Consult the "Brief Questionnaire to Identify Decision Stage" on the following page. This simple line of questioning to define a decision stage helps short-circuit lengthy and unnecessary discussion. The provider can respond to the patient's level of thinking and help with planning, focus on insurance issues, or address other barriers.

‡‡‡‡‡ The stage theories of change include the Transtheoretical Model of Behavior Change, the first of its type, developed by Prochaska and DiClemente (1983), with four stages (precontemplation, contemplation, action, maintenance), the Precaution Adoption Process Model studied by Weinstein, et. al. (1990), with seven stages, and the model shown here with five stages, developed by RE Myers

§§§§§ This version of stage theory was developed by RE Myers.

A Decision Stage Model for CRC Screening††††††††



†††††††† This version of stage theory was adapted from the work of by RE Myers.

Brief Questionnaire to Identify Decision Stage******

Use this questionnaire when starting a conversation with a patient about screening. It will help you identify the readiness of the patient for screening.

Describe the specific screening test – e.g., stool blood test , CT colonography (CTC), or colonoscopy (CS), etc.

1. Have you ever heard of a (stool blood test, CTC, CS)?
   Yes – Go on
   No – Stop (Stage 1)

2. Are you thinking about doing a (stool blood test, CTC, CS)?
   Yes – Go on
   No – Stop (Stage 2)

3. Which of the following statements best describes your thoughts about doing a (stool blood test, CTC, CS) in the future?
   a. I have decided against doing a (stool blood test, CTC, CS). (Stage 0)
   b. I'm thinking about whether or not to do a (stool blood test, CTC, CS). (Stage 2 or 3)
   c. I have decided to do a (stool blood test, CTC, CS). (Stage 4)

   Responses place the individual in a decision stage related to screening test use:

Stage 0: Decided against
Stage 1: Never heard of
Stage 2: Heard of – not considering
Stage 3: Heard of – considering
Stage 4: Heard of – decided to do

****** Source: Adapted from RE Myers, 2003

To reiterate, interactions based on a communication theory are more effective than generic education. In meta-analysis conducted on mammography screening, generic education was not demonstrated to be an effective approach. Theory-based education strategies produced a 24 percent increase in screening rates, compared to no increase for generic education strategies.[151]

In summary, due to the time pressures on contemporary practice, communications must be more efficient than ever before. Studies confirm what primary care physicians know well: There is less time to accomplish a larger number of objectives with each patient visit. Strategies and tools that improve efficiency are needed. Stage-based communications offer a valuable and accessible tool. They are logical, easy-to-understand and remember. In short, they are efficient and facilitate flow of the right information.[152]

Shared Decisions, Informed Decisions, Decision Aids

While most providers support the idea of shared decision-making, it has been shown that it is all too often neglected. Providers commonly fail to explore patient preferences and simply offer their own recommendations.[153] Documentation exists that patients do have preferences. In fact, patients express clear preferences for screening options that rest on the value they place on particular test features.[154] [155] Patients who place a high value on accuracy value a colonoscopy, which is the most sensitive and specific test. Patients who place a high value on convenience, privacy, or reassurance from frequent testing benefit from a home stool blood test kit. The existence of patient preference dictates that clinicians learn their patients' preferences and aim for a shared decision about the screening modality. Failure to do so puts the clinician at risk of being ineffective. There is evidence that patients prefer shared decision-making. A decision that is based on a patient's preference and guided by a physician is a shared decision.[156]

A tool that helps clinician and patient identify patient preferences should be helpful in producing a shared decision. Unfortunately, recommendations for screening are undermined by the mismatch between physicians who haven't explored patient preferences and patients who get recommendations that don't fit their preferences. Tools that will help produce the best, most informed decision – the decision to go ahead with screening – are greatly needed.

Decision-making tools that identify patient preference are under development with the support of the National Cancer Institute. Some tools are already showing promise. Studies have demonstrated that these tools help patients who start out undecided to identify their preference.[157] [158] [159] Within a few years, validated tools should be available. However, at this moment, few decision-making tools are ready for mass distribution.

Informed decisions are decisions in which patients are aware of their options and understand the risks and benefits. For those patients who are considering screening but would like additional information to help them make an informed decision, there are brochures, pamphlets, and Internet guides. The Internet also offers a great deal of useful information. Useful Web sites include www.healthfinder.gov and www.cancer.org. Communication systems with informational content can be upgraded in efficiency if they are delivered actively, and based on the "stages of intention" theory or another useful theory like the health belief model or social cognitive theory.[160 161 162]

Some decision aids are also available online. They may not yet be validated as effective but they do provide information. As described, these help an individual weigh the risks and benefits of different procedures. These can be found on the Internet at www.mayoclinic.com or http://my.webmd.com. An informed patient who has used a decision aid may be in a better position to share in decision making with their clinician. The American Cancer Society has developed for office use a video decision aid that reviews and demonstrates all screening options. Available in both English and Spanish, this tool can be found at www.cancer.org/colonmd.

Staff Involvement

The staff of your practice can contribute directly to expanded screening. The time that a patient spends with non-physician staff is under-utilized. This time can be used for a better purpose. Staff can play several different roles.

Standing orders can empower nurses and intake/discharge staff to give patients a stool blood test kit, a referral for endoscopy, or a complete diagnostic work-up after a positive screen based on patient needs, all without a doctor's immediate order. While in the waiting room, patients can be asked to fill out brief surveys that guide staff to a course of action. Surveys can include questions about risk factors, prior screening, and stage of intention regarding CRC screening. Subsequently, staff members who place patients in the exam room can then give them a "tailored" information sheet, geared to their decision stage and/or risk level and talk about it with them.

The time when the patient is placed in a room and prepared for the clinician encounter may also be useful for clarifying CRC risk level and asking the simple questions that define decision stage about screening. With the risk level and decision stage pinpointed, a targeted discussion with the clinician is facilitated. Non-physician staff can also encourage patients to get the needed screening tests. The discharge staff can provide referrals for flexible sigmoidoscopy (FS) or colonoscopy (CS) testing – or dispense stool blood test cards – as part of a chain of responsibility for the screening process.

Incorporating staff into this effort makes it easier to provide screening on an "opportunistic" basis, i.e., whenever patients come in. "Opportunistic" screening differs from screening that is arranged solely at the time of the annual checkup in that it can occur any time the patient visits the practice.[163] Grouping visits for patients who share the same category of increased risk is another approach that is being used to advance practice goals, including referrals for screening.[164] Letters, fold-over postcards, or phone calls may be used to invite those at increased risk for CRC to an individual or group visit – or to invite at-risk family members. In many cases, providers can bill insurers for each attendee for the preventive visit.

When staff are explicitly involved in making practice improvements, it becomes easier to achieve the desired goals. As described above under Office Reminder Systems: Staff Assignments, all staff can be included in regular meetings to examine and improve the process, receive education about the effort, and review the results.

TRACKING OFFICE PROGRESS

Progress can be tracked through repeat chart audits. New charts are chosen at random. This will allow for a comparison between subsequent audits and a baseline audit. Many practices choose 20 charts of age-appropriate patients for each clinician. The sample-size calculator mentioned above can also be used to choose an appropriate number. (This is available at the Web site of a Medicare quality of care contractor, www.cmri-ca.org.) Intervals of six months to a year may be appropriate, depending on how many patients age 50 and over visit the practice. The results of these audits can be shared with all the members of the staff team and used as the basis for discussion and planning. There are audit templates in Appendix D.

Physicians can also evaluate their systems for providing CRC screening by having regular staff meetings or eliciting patient feedback. Regular staff meetings allow for regular reports from staff on the progress of new procedures. They also give staff the opportunity to rehearse new skills, get continuing education, and explore ways to support one another.

There will be areas of strength and areas of deficiency of the practice. Areas of excellence should receive positive reinforcement and acknowledgement. Input helps develop solutions for deficiencies. An informal questionnaire can also help identify strengths and weaknesses. Please refer to the example.

Patient feedback can be elicited through suggestion boxes, focus groups, customer satisfaction surveys, or calls. Tracking your success with individual patients – or patients at increased risk – is another important quality approach. A tracking template is found in Appendix D.

Internal Practice Questionnaire

Goals

Are we functioning in alignment with our greater purpose? Our vision?

Do we need to reevaluate our goals?

What is working well? Why?

What is not working? Why?

What can be done differently?

Are we providing the services we said we wanted to provide?

Should we reevaluate the services we offer?

Materials

How do the cancer prevention materials fit our needs?

Should we modify any of the cancer prevention materials?

Documentation

Are we documenting the services we provide?

Staff Performance and Satisfaction

How are the staff performing their functions?

Are staff stepping in where needed?

Are staff working together as a team?

Are all staff contributing suggestions?

How do staff members feel about their work?

Do staff members feel supported and heard?

Patients

How are our patients responding to the change?

Source: Agency for Healthcare Research and Quality.

Conclusion

- Colorectal cancer is the second leading cause of cancer deaths in the United States, even though it is largely preventable.
- A physician's recommendation is the most powerful influence on individual patient decisions to undergo cancer screening.
- Risk management concerns and new insurance reporting requirements dictate improved cancer screening rates.
- This guide will help you realize the potential for making a difference in colorectal cancer incidence and mortality.
- Office practice routines can be altered to attain a high level of consistency in getting screening recommendations to patients.
- Four elements are essential to improved screening.
- The evidence-based strategies and tools in this guide will help make your practice more effective.

Conclusion

Colorectal cancer (CRC) is the second leading cause of cancer deaths in the United States, even though it is largely preventable. If CRC screening were universal – beginning at age 50 for those at average risk and earlier for those at increased risk – with timely removal of adenomas and early cancers, the mortality from CRC could be drastically reduced. Health care disparities in colorectal incidence and mortality would also be dramatically reduced.

A physician's recommendation is one of the most powerful influences on individual patient decisions to undergo cancer screening. While 98 percent of primary physicians do recommend CRC screening to their patients, most physicians do not convey a recommendation to every patient who warrants it. Only a systematic approach that is specifically designed to identify and provide a recommendation to every eligible patient who visits the practice for any reason is likely to succeed.

Risk management concerns and new insurance reporting requirements are other strong reasons to pursue improvement in CRC screening rates. Dollar awards place CRC in the top five malpractice targets nationwide. As of 2006, CRC screening rates were being reported to the public under the Health Plan Employer Data and Information Set (HEDIS) reporting requirements of the National Committee on Quality Assurance. Continuing medical education (CME) credit is now available for practice improvement activities.

Where there are barriers to improvement in CRC screening, they need to be actively addressed. Outdated knowledge must be updated, and changes in the guidelines must be understood. Inconsistencies in the guidelines are exaggerated and misunderstood. Lack of confidence in the efficacy of screening is unwarranted, and there is little evidence that any of the recommended screening tests are not acceptable to patients.

While lack of health insurance and absence of a regular source of care are real barriers to screening, a stool blood test is affordable to almost everyone. The provider of the stool blood test may be harder to come by at low cost. Stool blood tests are now available over-the-counter in some pharmacies during screening campaigns. Still, colonoscopy procedures are needed for those who have a positive stool blood test, and there is little remedy for those who lack access or payment for colonoscopy. Another barrier is confusion about priorities and goals. Colorectal cancers are found in about 1 percent of screenings, but adenomatous polyps are found in about 20 percent of all colonoscopies. Removal of the adenomatous polyp prevents the development of the cancer.

This guide will help you make a difference in the incidence and mortality from colorectal cancer. The key to success is the screening recommendation. Office practice routines can be altered to create systems that attain a high level of consistency in getting screening recommendations to patients. This guide is intended to assist physicians and their office managers build a practice that has such consistency. While the overwhelming majority of primary care doctors screen for colorectal cancer, few would say that every eligible patient leaves the practice with the needed recommendation. It is not enough to know what needs to be done. It is doing it that makes a difference. The evidence-based tools and strategies in this guide can move your practice to a higher level of performance.

There are four elements that are essential to improve the effectiveness of the practice.

1. **A Recommendation.** Doctors should recommend screening to every appropriate patient according to accepted guidelines and their own office policy. This is the single most important element in increasing screening rates.

2. **An Office Policy.** An office policy is necessary to assure that every appropriate patient receives a recommendation. The policy incorporates the considerations of risk level, local medical resources, patient health care insurance coverage, and local standards of care; it also provides ongoing guidance to the members of the practice and the staff about how to proceed. A high level of success in achieving follow-through on complete diagnostic workups for those who screen positive is another important objective. This has frequently been a weak point in the system. Without this step, the benefits of screening will not be realized.

3. **A Reminder System.** Reminder systems can be directed at patients, at providers, or both. Evidence has demonstrated that all types of reminder systems directed at physicians can be effective. Some of those directed at patients are also effective.

4. **An Effective Communication System.** Effective communications are a key link in the chain that produces desired health outcomes. Stage-based models provide simple tools that can be used in practice so that the face time of the doctor is directed to the most pivotal issue. Patient buy-in is key. Many patients do have preferences where there is a reasonable choice to be made. Informed decisions and shared decisions are preferred to simple physician directives. Decision-making tools are under development. Patient education that is based on a theory (i.e., stage theory) is more effective than generic education. Theory-based models make it easier to reproduce an approach over and over again with tools that ensure consistency and thoroughness.

Tracking the improvements made by the practice is the only way to be sure that it has happened. CME credit is now available for such efforts.

Appendix A:

Current Screening Guidelines

Current Screening Guidelines

- Common Sense Colorectal Cancer Screening Recommendations at a Glance
- Guidelines of the American Cancer Society, the US Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology
- Guidelines of the US Preventive Services Task Force
- Guidelines article of the American Cancer Society, the US Multi-Society Task Force, and the American College of Radiology
- Guidelines article for Surveillance after Polypectomy from the US Multi-Society Task Force and the American Cancer Society
- Guidelines article for Surveillance after Cancer Resection from the American Cancer Society and the US Multi-Society Task Force

Common Sense Colorectal Cancer Screening Recommendations[1] at a Glance

Risk Category	Age to Begin Screening	Recommendations
Average risk No risk factors No symptoms[2]	**< Age 50** **≤ Age 50**	**No screening needed** **Screen with any one of the following options:** *Tests That Find Polyps and Cancer* FS q 5 yrs* CS q 10 yrs DCBE q 5 yrs* CTC q 5 yrs* OR *Tests That Primarily Find Cancer* gFOBT q 1 yr*,** FIT q 1 yr*,** sDNA***
Increased risk CRC or adenomatous polyp in a first-degree relative[3]	**Age 40 or 10 years younger than the earliest diagnosis in the family, whichever comes first**	**Colonoscopy[4]**
Highest risk Personal history for > 8 years of Crohn's disease or ulcerative colitis or a hereditary syndrome (HNPCC or, FAP, AFAP)	**Any age**	**Needs specialty evaluation and colonoscopy**

* If the test is positive, a colonoscopy should be done.
** The multiple stool take-home test should be used. One test done by the doctor in the office is not adequate for testing.
*** Interval uncertain.

The tests that are designed to find both early cancer and polyps are preferred if these tests are available and the patient is willing to have one of these more invasive tests.

1. Patients with a personal history of CRC or adenomatous polyp require a surveillance plan not screening.
2. Patients with symptoms merit an evaluation of their condition to precede screening.
3. The American Cancer Society and the US Multi-Society Task Force on Colorectal Cancer view a patient as being at average risk for the purpose of screening if only one first degree relative (FDR) > age 60 is affected. If the FDR is <50, or affected, also check for a history consistent with hereditary non-polyposis colorectal cancer. The criteria (Revised Amsterdam) for HNPCC are that there should be at least three relatives with HNPCC-associated cancers (colorectal, endometrium, small bowel, ureter, renal pelvis) and all of the following criteria must be met: 1) One should be a first-degree relative of the other two. 2) At least two successive generations should be affected. 3) At least one cancer should be diagnosed before age 50. 4) Familial adenomatous polyposis should be excluded in the CRC case. 5) Tumors should be verified by pathological examination.
4. Colonoscopy for persons at increased risk is the recommendation of the American Cancer Society and the US Multi-Society Task Force on Colorectal Cancer. The US Multi-Society Task Force on Colorectal Cancer recommends repeat every five years, the American Cancer Society every five to10 years. The US Preventive Services Task Force (USPSTF) does not specifically recommend colonoscopy, but notes that colonoscopy is the most sensitive and specific modality.

Source: Adapted by the author from the guidelines of the Maryland State Cancer Programs (2005) and national guidelines.

TABLE **2** Guidelines for Screening for the Early Detection of Colorectal Cancer and Adenomas for Average-risk Women and Men Aged 50 Years and Older

The following options are acceptable choices for colorectal cancer screening in average-risk adults beginning at age 50 years. Since each of the following tests has inherent characteristics related to prevention potential, accuracy, costs, and potential harms, individuals should have an opportunity to make an informed decision when choosing one of the following options.

In the opinion of the guidelines development committee, *colon cancer prevention* should be the primary goal of colorectal cancer screening. Tests that are designed to detect both early cancer and adenomatous polyps should be encouraged if resources are available and patients are willing to undergo an invasive test.

Tests that Detect Adenomatous Polyps and Cancer

Test	Interval	Key Issues for Informed Decisions
FSIG with insertion to 40 cm or to splenic flexure	Every 5 years	• Complete or partial bowel prep is required • Sedation usually is not used, so there may be some discomfort during the procedure • The protective effect of sigmoidoscopy is primarily limited to the portion of the colon examined • Patients should understand that positive findings on sigmoidoscopy usually result in a referral for colonoscopy
Colonoscopy	Every 10 years	• Complete bowel prep is required • Conscious sedation is used in most centers; patients will miss a day of work and will need a chaperone for transportation from the facility • Risks include perforation and bleeding, which are rare but potentially serious; most of the risk is associated with polypectomy
DCBE	Every 5 years	• Complete bowel prep is required • If patients have one or more polyps ≥6 mm, colonoscopy will be recommended; follow-up colonoscopy will require complete bowel prep • Risks of DCBE are low; rare cases of perforation have been reported
CTC	Every 5 years	• Complete bowel prep is required • If patients have one or more polyps ≥6 mm, colonoscopy will be recommended; if same day colonoscopy is not available, a second complete bowel prep will be required before colonoscopy • Risks of CTC are low; rare cases of perforation have been reported • Extracolonic abnormalities may be identified on CTC that could require further evaluation

Tests that Primarily Detect Cancer

Test	Interval	Key Issues for Informed Decisions
gFOBT with high sensitivity for cancer	Annual	• Depending on manufacturer's recommendations, 2 to 3 stool samples collected at home are needed to complete testing; a single sample of stool gathered during a digital exam in the clinical setting is not an acceptable stool test and should not be done
FIT with high sensitivity for cancer	Annual	• Positive tests are associated with an increased risk of colon cancer and advanced neoplasia; colonoscopy should be recommended if the test results are positive • If the test is negative, it should be repeated annually • Patients should understand that one-time testing is likely to be ineffective
sDNA with high sensitivity for cancer	Interval uncertain	• An adequate stool sample must be obtained and packaged with appropriate preservative agents for shipping to the laboratory • The unit cost of the currently available test is significantly higher than other forms of stool testing • If the test is positive, colonoscopy will be recommended • If the test is negative, the appropriate interval for a repeat test is uncertain

Abbreviations: FSIG, flexible sigmoidoscopy; DCBE, double-contrast barium enema; CTC, computed tomography colonography; gFOBT, guaiac-based fecal occult blood test; FIT, fecal immunochemical test; sDNA, stool DNA test.

TABLE **3** Guidelines for Screening and Surveillance for the Early Detection of Colorectal Adenomas and Cancer in Individuals at Increased Risk or at High Risk

Risk Category	Age to Begin	Recommendation	Comment
Increased Risk—Patients with History of Polyps at Prior Colonoscopy			
Patients with small rectal hyperplastic polyps[26]	—	Colonoscopy or other screening options at intervals recommended for average-risk individuals	An exception is patients with a hyperplastic polyposis syndrome. They are at increased risk for adenomas and colorectal cancer and need to be identified for more intensive follow up.
Patients with 1 or 2 small tubular adenomas with low-grade dysplasia[26]	5 to 10 years after the initial polypectomy	Colonoscopy	The precise timing within this interval should be based on other clinical factors (such as prior colonoscopy findings, family history, and the preferences of the patient and judgment of the physician).
Patients with 3 to 10 adenomas or 1 adenoma >1 cm or any adenoma with villous features or high-grade dysplasia[26]	3 years after the initial polypectomy	Colonoscopy	Adenomas must have been completely removed. If the follow-up colonoscopy is normal or shows only 1 or 2 small, tubular adenomas with low-grade dysplasia, then the interval for the subsequent examination should be 5 years.
Patients with >10 adenomas on a single examination[26]	<3 years after the initial polypectomy	Colonoscopy	Consider the possibility of an underlying familial syndrome.
Patients with sessile adenomas that are removed piecemeal[26]	2 to 6 months to verify complete removal	Colonoscopy	Once complete removal has been established, subsequent surveillance needs to be individualized based on the endoscopist's judgment. Completeness of removal should be based on both endoscopic and pathologic assessments.
Increased Risk—Patients with Colorectal Cancer			
Patients with colon and rectal cancer should undergo high-quality perioperative clearing[25]	3 to 6 months after cancer resection, if no unresectable metastases are found during surgery; alternatively, colonoscopy can be performed intraoperatively	Colonoscopy	In the case of nonobstructing tumors, this can be done by preoperative colonoscopy. In the case of obstructing colon cancers, CTC with intravenous contrast or DCBE can be used to detect neoplasms in the proximal colon.
Patients undergoing curative resection for colon or rectal cancer[2]	1 year after the resection (or 1 year following the performance of the colonoscopy that was performed to clear the colon of synchronous disease)	Colonoscopy	This colonoscopy at 1 year is in addition to the perioperative colonoscopy for synchronous tumors. If the examination performed at 1 year is normal, then the interval before the next subsequent examination should be 3 years. If that colonoscopy is normal, then the interval before the next subsequent examination should be 5 years. Following the examination at 1 year, the intervals before subsequent examinations may be shortened if there is evidence of HNPCC or if adenoma findings warrant earlier colonoscopy. Periodic examination of the rectum for the purpose of identifying local recurrence, usually performed at 3- to 6-month intervals for the first 2 or 3 years, may be considered after low-anterior resection of rectal cancer.
Increased Risk—Patients with a Family History			
Either colorectal cancer or adenomatous polyps in a first-degree relative before age 60 years or in 2 or more first-degree relatives at any age[24]	Age 40 years or 10 years before the youngest case in the immediate family	Colonoscopy	Every 5 years
Either colorectal cancer or adenomatous polyps in a first-degree relative ≥age 60 years or in 2 second-degree relatives with colorectal cancer[24]	Age 40 years	Screening options at intervals recommended for average-risk individuals	Screening should begin at an earlier age, but individuals may choose to be screened with any recommended form of testing.

TABLE **3** (continued)

Risk Category	Age to Begin	Recommendation	Comment
High Risk			
Genetic diagnosis of FAP or suspected FAP without genetic testing evidence[24]	Aged 10 to 12 years	Annual FSIG to determine if the individual is expressing the genetic abnormality and counseling to consider genetic testing.	If the genetic test is positive, colectomy should be considered.
Genetic or clinical diagnosis of HNPCC or individuals at increased risk of HNPCC[24]	Aged 20 to 25 years or 10 years before the youngest case in the immediate family	Colonoscopy every 1 to 2 years and counseling to consider genetic testing	Genetic testing for HNPCC should be offered to first-degree relatives of persons with a known inherited MMR gene mutation. It should also be offered when the family mutation is not already known, but 1 of the first 3 of the modified Bethesda Criteria is present.
Inflammatory bowel disease,[24] chronic ulcerative colitis, and Crohn's colitis	Cancer risk begins to be significant 8 years after the onset of pancolitis or 12 to 15 years after the onset of left-sided colitis	Colonoscopy with biopsies for dysplasia	Every 1 to 2 years; these patients are best referred to a center with experience in the surveillance and management of inflammatory bowel disease

Abbreviations: FSIG, flexible sigmoidoscopy; DCBE, double-contrast barium enema; CTC, computed tomographic colonography; FAP, familial adenomatous polyposis; HNPCC, hereditary nonpolyposis colon cancer; MMR, mismatch repair.

U.S. Preventive Services Task Force Summary of Colorectal Cancer Screening Recommendations

The U.S. Preventive Services Task Force (USPSTF) strongly recommends that clinicians screen men and women 50 years of age or older for colorectal cancer. There are insufficient data to determine which strategy is best in terms of the balance of benefits and potential harms or cost-effectiveness. Studies reviewed by the USPSTF indicate that colorectal cancer screening is likely to be cost-effective (less than $30,000 per additional year of life gained) regardless of the strategy chosen.

Test	Interval (Beginning at age 50)	Comment
Fecal Occult Blood Test (FOBT) and Flexible Sigmoidoscopy	FOBT every year plus flexible sigmoidoscopy at an unspecified interval	The combination of FOBT and sigmoidoscopy may detect more cancers and more large polyps than either test alone, but the additional benefits and potential harms of combining the two tests are uncertain. In general, FOBT should precede sigmoidoscopy because a positive test result is an indication for colonoscopy, obviating the need for sigmoidoscopy.
Flexible Sigmoidoscopy	Unspecified interval	Although sigmoidoscopy can only visualize the lower half of the colon, it has been estimated to identify 80 percent of all patients with significant findings in the colon, because findings on sigmoidoscopy will trigger examination of the entire colon.
Fecal Occult Blood Test (FOBT)	Every year	Proven methods of FOBT screening use guaiac-based test cards prepared at home by patients from three consecutive stool samples and forwarded to the clinician. Whether patients need to restrict their diet and avoid certain medications is not established. Rehydration of the specimens before testing increases the sensitivity of FOBT but substantially increases the number of false-positive test results.
Colonoscopy	Unspecified interval	The USPSTF did not find direct evidence that screening colonoscopy is effective in reducing colorectal cancer mortality. Efficacy of colonoscopy is supported by its integral role in trials of FOBT, extrapolation from sigmoidoscopy studies, limited case-control evidence, and the ability of colonoscopy to inspect the proximal colon.
Double-Contrast Barium Enema (DCBE)	Unspecified interval	Double-contrast barium enema offers an alternative means of whole-bowel examination, but it is less sensitive than colonoscopy, and there is no direct evidence that it is effective in reducing mortality rates.

SOURCE: U.S. Preventive Services Task Force, 2002.

Screening and Surveillance for the Early Detection of Colorectal Cancer and Adenomatous Polyps, 2008: A Joint Guideline from the American Cancer Society, the US Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology*†

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ABSTRACT In the United States, colorectal cancer (CRC) is the third most common cancer diagnosed among men and women and the second leading cause of death from cancer. CRC largely can be prevented by the detection and removal of adenomatous polyps, and survival is significantly better when CRC is diagnosed while still localized. In 2006 to 2007, the American Cancer Society, the US Multi Society Task Force on Colorectal Cancer, and the American College of Radiology came together to develop consensus guidelines for the detection of adenomatous polyps and CRC in asymptomatic average-risk adults. In this update of each organization's guidelines, screening tests are grouped into those that primarily detect cancer early and those that can detect cancer early and also can detect adenomatous polyps, thus providing a greater potential for prevention through polypectomy. When possible, clinicians should make patients aware of the full range of screening options, but at a minimum they should be prepared to offer patients a choice between a screening test that is effective at both early cancer detection and cancer prevention through the detection and removal of polyps and a screening test that primarily is effective at early cancer detection. It is the strong opinion of these 3 organizations that colon cancer prevention should be the primary goal of screening. (*CA Cancer J Clin 2008;58:130–160.*) *© American Cancer Society, Inc., 2008.*

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INTRODUCTION

In the United States, colorectal cancer (CRC) is the third most common cancer diagnosed in men and women and the second leading cause of death from cancer.[1] In 2008, it is estimated that 148,810 men and women will be diagnosed with CRC and 49,960 will die from this disease.[1] Five-year survival is 90% if the disease is diagnosed while still localized (ie, confined to the wall of the bowel), but only 68% for regional disease (ie, disease with lymph node involvement), and only 10% if distant metastases are present.[2] Recent trends in CRC incidence and mortality reveal declining rates, which have been attributed to reduced exposure to risk factors, screening's effect on early detection and prevention through polypectomy, and improved treatment.[3] However, in the near term, even greater incidence and mortality reductions could be achieved if a greater proportion of adults received regular screening. Although prospective randomized trials and observational studies have demonstrated mortality reductions associated with early detection of invasive disease, as well as removal of adenomatous polyps,[4–7] a majority of US adults are not receiving regular age- and risk-appropriate screening or have never been screened at all.[8,9]

The goal of cancer screening is to reduce mortality through a reduction in incidence of advanced disease. To this end, modern CRC screening can achieve this goal through the detection of early-stage adenocarcinomas and the detection and removal of adenomatous polyps, the latter generally accepted as nonobligate precursor lesions. Adenomatous polyps are common in adults over age 50 years, but the majority of polyps will not develop into adenocarcinoma; histology and size determine their clinical importance.[10,11] The most common and clinically important polyps are adenomatous polyps, which represent approximately one-half to two-thirds of all colorectal polyps and are associated with a higher risk of CRC. Thus, most CRC screening studies evaluate the detection rate of invasive CRC, as well as advanced adenomas, which conventionally are defined as polyps greater than or equal to 10 mm or histologically having high-grade dysplasia or significant villous components. The evidence for the importance of colorectal polyps in the development of CRC is largely indirect, but nonetheless extensive and convincing, and has been described in detail.[11–13]

Today there is a range of options for CRC screening in the average-risk population, with current technology falling into 2 general categories: stool tests, which include tests for occult blood or exfoliated DNA; and structural exams, which include flexible sigmoidoscopy (FSIG), colonoscopy, double-contrast barium enema (DCBE), and computed tomographic colonography (CTC). Stool tests are best suited for the detection of cancer, although they also will deliver positive findings for some advanced adenomas, while the structural exams can achieve the dual goals of detecting adenocarcinoma as well as identifying adenomatous polyps.[14] These tests may be used alone or in combination to improve sensitivity or, in some instances, to ensure a complete examination of the colon if the initial test cannot be completed. Although screening tests for CRC vary in terms of the degree of supporting evidence, potential efficacy for incidence and mortality reduction, cost-effectiveness, and acceptability, any one of these options applied in a systematic program of regular screening has the potential to significantly reduce deaths from CRC.

Beginning in 1980, the American Cancer Society (ACS) first issued formal guidelines for CRC screening in average-risk adults.[15] Since then, the ACS has periodically updated its CRC guidelines,[16–19] including adding recommendations for high-risk individuals in 1997.[17] Other organizations also have issued recommendations for CRC screening, most notably the US Preventive Services Task Force,[20,21] the American College of Radiology (ACR),[22,23] and the US Multi-Society Task Force on Colorectal Cancer (USMSTF).[12,24] Recently, the ACS and the USMSTF collaborated on an update of earlier recommendations for postpolypectomy and post-CRC resection surveillance in response to reports suggesting significant deviation from existing recommendations.[25,26] Since 1997, the organizational guidelines for average-risk adults have grown increasingly similar and represent a broad organizational consensus on the value, options, and methods for periodic screening for CRC.

In the last decade, there has been an increase in the number of technologies available for CRC screening, and in the case of stool tests, there has been growth in the number of commercial versions of guaiac-based and immunochemical-based stool tests (gFOBT and FIT). This growth in options also has been accompanied by changing patterns in the proportion of adults using different tests, with FSIG rates declining, colonoscopy rates increasing, use of stool blood tests remaining somewhat constant, and use of the DCBE for screening now becoming very uncommon.[8]

There are pros and cons to having a range of options for CRC screening. Despite the fact that the primary barriers to screening are lack of health insurance, lack of physician recommendation, and lack of awareness of the importance of CRC screening,[27] the historical evidence shows that adults have different preferences and patterns of use among the available CRC screening tests.[28–31] Although population preferences or resistance to a particular technology may change over time or may be influenced by referring physicians, it also may be true that over time some adults may persist in choosing one technology and rejecting another. Furthermore, at this time not all options are available to the entire population, and transportation, distance, and financial barriers to some screening technologies may endure for some time. Although in principle all adults should have access to the full range of options for CRC screening, the fact that simpler, lower-cost options are available in most settings, whereas other more costly options are not universally available, is a public health advantage. However, for average-risk adults, multiple testing options challenge the referring physician to support an office policy that can manage a broad range of testing choices, their follow-up requirements, and shared decision making related to the options. Shared decision making for multiple screening choices is both demanding and time consuming and is complicated by the different characteristics of the tests and the test-specific requirements for individuals undergoing screening.[31] In addition, the description of benefits is complicated by different performance characteristics of the variants of the occult blood tests and uncertain differences between test performance in research settings and test performance in clinical practice. These challenges have been discussed in the past,[19,32] and they still are with us today.

In this guideline review, we have reassessed the individual test evidence and comparative evidence for stool tests, including gFOBT, FIT, and stool DNA test (sDNA), and the structural exams, including FSIG, colonoscopy, DCBE, and CTC, the latter also known as virtual colonoscopy. We have sought to address a number of concerns about the complexity of offering multiple screening options and the degree to which the range of screening options and their performance, costs, and demands on individuals poses a significant challenge for shared decisions. An overriding goal of this update is to provide a practical guideline for physicians to assist with informed decision making related to CRC screening. These guidelines are for individuals at average risk. Individuals with a personal or family history of CRC or adenomas, inflammatory bowel disease, or high-risk genetic syndromes should continue to follow the most recent recommendations for individuals at increased or high risk.[24–26]

GUIDELINES DEVELOPMENT, METHODS, AND FRAMEWORK

The guidelines update process was divided into 2 phases. The first phase focused on the stool tests, including gFOBT, FIT, and sDNA. The second phase of the guidelines update process focused on the structural exams, including FSIG, colonoscopy, DCBE, and CTC. Deliberations about evidence and presentations from experts took place during 2 face-to-face meetings of the the collaborating organizations and invited outside experts and through periodic conference calls. The process relied on earlier evidence-based reviews.[12,16–21,24] Literature related to CRC screening and specific to individual tests published between January 2002 and March 2007 was identified using MEDLINE (National Library of Medicine) and bibliographies of identified articles. Expert panel members also provided several unpublished abstracts and manuscripts. Where evidence was insufficient or lacking to provide a clear, evidence-based conclusion, final recommendations were based on expert opinion and are so indicated.

While there is clear experimental evidence that screening for CRC with gFOBT is associ-

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ated with reduced incidence and mortality from CRC screening,[5,6,33] most of the information supporting the use of the other colorectal screening tests is based on observational and inferential evidence. In this review, priority was placed on studies of asymptomatic average-risk or higher-risk populations that were followed by testing with colonoscopy in all or nearly all study participants as a validation measure.

SUMMARY OF THE RECOMMENDATIONS

In this update of guidelines for CRC screening in average risk-adults, the expert panel concluded that a screening test must be able to detect the majority of prevalent or incident cancers at the time of testing. Here we are drawing a new, important distinction between test sensitivity and program sensitivity, the former being the sensitivity achieved in a single test and the latter being the sensitivity achieved over time through serial testing in a program. While cancer screening tests are expected to achieve acceptable levels of sensitivity and specificity,[34] no specific acceptance threshold for either measure, alone or in combination, has been established for any screening test.[35,36] Thus, this criterion is based on expert opinion and the following considerations. First, in the judgment of the panel, recent evidence has revealed an unacceptably wide range of sensitivity among some gFOBT strategies, with some practices and tests performing so poorly that the large majority of prevalent cancers are missed at the time of screening.[37–39] The observation of very low sensitivity for cancer and advanced neoplasia associated with in-office gFOBT led Sox to speculate that CRC mortality rates might be considerably lower today if the quality of gFOBT testing during the previous decade had been higher.[40] While the literature on other CRC screening tests also reveals a range of sensitivities, even in the presence of significant, correctable, quality-related shortcomings, the majority of invasive cancers still will be detected. Second, a test like gFOBT that demonstrates poor test sensitivity but good program sensitivity depends on high rates of adherence with regular screening. However, many patients have only one test and do not return the following year for programmatic testing.[41,42] Given the lack of systems to ensure or at least facilitate adherence with recommended regular screening intervals, as well as evidence of suboptimal awareness and engagement of primary care in supporting adherence with screening recommendations,[43] the panel concluded that it was not realistic at this time to rely on program sensitivity to overcome limitations in test sensitivity. Physicians and institutions should select stool blood tests that have been shown in the scientific literature to detect the majority of prevalent CRC in an asymptomatic population. If there is not evidence that an available test has met that benchmark, it should not be offered to patients for CRC screening.

Individuals and health care professionals should also understand that screening tests for CRC broadly fall into 2 categories. In one category are the fecal tests (ie, gFOBT, FIT, and sDNA), which are tests that primarily are effective at identifying CRC. Some premalignant adenomatous polyps may be detected, providing an opportunity for polypectomy and the prevention of CRC, but the opportunity for prevention is both limited and incidental and is not the primary goal of CRC screening with these tests. In the second category are the partial or full structural exams (ie, FSIG, colonoscopy, DCBE, and CTC),[44] which are tests that are effective at detecting cancer and premalignant adenomatous polyps. These tests differ in complexity and accuracy for the detection of CRC and advanced neoplasia. When performed properly, each of these structural exams has met the standard of detecting at least half of prevalent or incident cancers at the time of testing.

It is the strong opinion of this expert panel that *colon cancer prevention* should be the primary goal of CRC screening. Tests that are designed to detect both early cancer and adenomatous polyps should be encouraged if resources are available and patients are willing to undergo an invasive test. These tests include the partial or full structural exams mentioned above. These tests require bowel preparation and an office or hospital visit and have various levels of risk to patients. These tests also have limitations, greater patient requirements for successful completion, and potential harms. Significant positive findings on FSIG, DCBE, and CTC require follow-up colonoscopy.

TABLE 1 Testing Options for the Early Detection of Colorectal Cancer and Adenomatous Polyps for Asymptomatic Adults Aged 50 Years and Older

Tests that Detect Adenomatous Polyps and Cancer
Flexible sigmoidoscopy every 5 years, or
Colonoscopy every 10 years, or
Double-contrast barium enema every 5 years, or
Computed tomographic colonography every 5 years
Tests that Primarily Detect Cancer
Annual guaiac-based fecal occult blood test with high test sensitivity for cancer, or
Annual fecal immunochemical test with high test sensitivity for cancer, or
Stool DNA test with high sensitivity for cancer, interval uncertain

The panel recognized that some patients will not want to undergo an invasive test that requires a bowel preparation, may prefer to have screening in the privacy of their home, or may not have access to the invasive tests due to lack of coverage or local resources. Collection of fecal samples for blood or DNA testing can be performed at home, without bowel preparation. However, providers and patients should understand the following limitations and requirements of noninvasive tests:

- These tests are less likely to prevent cancer compared with the invasive tests;
- These tests must be repeated at *regular* intervals to be effective;
- If the test is abnormal, an invasive test (colonoscopy) will be needed.

If patients are not willing to have repeated testing or have colonoscopy if the test is abnormal, these programs will not be effective and should not be recommended.

Based on our review of the historic and recent evidence, the tests in Table 1 are acceptable options for the early detection of CRC and adenomatous polyps for asymptomatic adults aged 50 years and older (also see Table 2).

SCREENING TESTS FOR THE DETECTION OF CRC

Stool Blood Tests—gFOBT and FIT

Stool blood tests are conventionally known as fecal occult blood tests (FOBT) because they are designed to detect the presence of occult blood in stool. FOBT fall into 2 primary categories based on the detected analyte: gFOBT and FIT. Blood in the stool is a nonspecific finding but may originate from CRC or larger (>1 to 2 cm) polyps. Because small adenomatous polyps do not tend to bleed and bleeding from cancers or large polyps may be intermittent or simply not always detectable in a single sample of stool, the proper use of stool blood tests requires annual testing that consists of collecting specimens (2 or 3, depending on the product) from consecutive bowel movements.[18,24,45] FIT generally are processed only in a clinical laboratory, whereas gFOBT are processed either in the physician's office or in a clinical laboratory. When performed for CRC screening, a positive gFOBT or FIT requires a diagnostic workup with colonoscopy to examine the entire colon in order to rule out the presence of cancer or advanced neoplasia.

gFOBT

gFOBT are the most common stool blood tests in use for CRC screening and the only CRC screening tests for which there is evidence of efficacy from prospective, randomized controlled trials. Guaiac-based tests detect blood in the stool through the pseudoperoxidase activity of heme or hemoglobin, while immunochemical-based tests react to human globin. The usual gFOBT protocol consists of collecting 2 samples from each of 3 consecutive bowel movements at home. Prior to testing with a sensitive guaiac-based test, individuals usually will be instructed to avoid aspirin and other nonsteroidal anti-inflammatory drugs, vitamin C, red meat, poultry, fish, and some raw vegetables because of diet-test interactions that can increase the risk of both false-positive and false-negative (specifically, vitamin C) results.[46] Collection of all 3 samples is important because test sensitivity improves with each additional stool sample.[14]

gFOBT—Efficacy and Test Performance. Three large, prospective, randomized controlled trials with gFOBT have demonstrated that screened patients have cancers detected at an early and more curable stage than unscreened patients. Over time (8 to 13 years), each of the trials demonstrated significant reductions in CRC mortality of 15% to 33%.[5,6,34] Moreover, inci-

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TABLE **2** Guidelines for Screening for the Early Detection of Colorectal Cancer and Adenomas for Average-risk Women and Men Aged 50 Years and Older

The following options are acceptable choices for colorectal cancer screening in average-risk adults beginning at age 50 years. Since each of the following tests has inherent characteristics related to prevention potential, accuracy, costs, and potential harms, individuals should have an opportunity to make an informed decision when choosing one of the following options.

In the opinion of the guidelines development committee, *colon cancer prevention* should be the primary goal of colorectal cancer screening. Tests that are designed to detect both early cancer and adenomatous polyps should be encouraged if resources are available and patients are willing to undergo an invasive test.

Tests that Detect Adenomatous Polyps and Cancer

Test	Interval	Key Issues for Informed Decisions
FSIG with insertion to 40 cm or to splenic flexure	Every 5 years	• Complete or partial bowel prep is required • Sedation usually is not used, so there may be some discomfort during the procedure • The protective effect of sigmoidoscopy is primarily limited to the portion of the colon examined • Patients should understand that positive findings on sigmoidoscopy usually result in a referral for colonoscopy
Colonoscopy	Every 10 years	• Complete bowel prep is required • Conscious sedation is used in most centers; patients will miss a day of work and will need a chaperone for transportation from the facility • Risks include perforation and bleeding, which are rare but potentially serious; most of the risk is associated with polypectomy
DCBE	Every 5 years	• Complete bowel prep is required • If patients have one or more polyps ≥6 mm, colonoscopy will be recommended; follow-up colonoscopy will require complete bowel prep • Risks of DCBE are low; rare cases of perforation have been reported
CTC	Every 5 years	• Complete bowel prep is required • If patients have one or more polyps ≥6 mm, colonoscopy will be recommended; if same day colonoscopy is not available, a second complete bowel prep will be required before colonoscopy • Risks of CTC are low; rare cases of perforation have been reported • Extracolonic abnormalities may be identified on CTC that could require further evaluation

Tests that Primarily Detect Cancer

Test	Interval	Key Issues for Informed Decisions
gFOBT with high sensitivity for cancer	Annual	• Depending on manufacturer's recommendations, 2 to 3 stool samples collected at home are needed to complete testing; a single sample of stool gathered during a digital exam in the clinical setting is not an acceptable stool test and should not be done • Positive tests are associated with an increased risk of colon cancer and advanced neoplasia; colonoscopy should be recommended if the test results are positive • If the test is negative, it should be repeated annually • Patients should understand that one-time testing is likely to be ineffective
FIT with high sensitivity for cancer	Annual	
sDNA with high sensitivity for cancer	Interval uncertain	• An adequate stool sample must be obtained and packaged with appropriate preservative agents for shipping to the laboratory • The unit cost of the currently available test is significantly higher than other forms of stool testing • If the test is positive, colonoscopy will be recommended • If the test is negative, the appropriate interval for a repeat test is uncertain

Abbreviations: FSIG, flexible sigmoidoscopy; DCBE, double-contrast barium enema; CTC, computed tomography colonography; gFOBT, guaiac-based fecal occult blood test; FIT, fecal immunochemical test; sDNA, stool DNA test.

dence reduction of 20% was demonstrated in one trial (Minnesota) after 18 years of follow up, which has been attributed to relatively higher rates of colonoscopy in the study (38% of subjects in the screened group).[7]

The sensitivity and specificity of a gFOBT has been shown to be highly variable and varies based on the brand or variant of the test[47]; specimen collection technique[38]; number of samples collected per test[14]; whether or not the stool specimen is rehydrated (ie, adding a drop of water to the slide window before processing)[48]; and variations in interpretation, screening interval, and other factors.[46]

The reported sensitivity of a single gFOBT varies considerably. In a review by Allison and

colleagues, sensitivity for cancer ranged from 37.1% for unrehydrated Hemoccult II to 79.4% for Hemoccult SENSA.[47] Lieberman and Weiss compared one-time testing with rehydrated Hemoccult II and observed 35.6% sensitivity for cancer.[14] In a study comparing gFOBT (unrehydrated Hemoccult II) with sDNA, sensitivity for cancer was only 12.9%.[37] More recently, Allison and colleagues compared a high-sensitivity gFOBT (Hemoccult SENSA) with an FIT and observed 64.3% sensitivity for cancer and 41.3% for advanced adenomas.[49] Thus, the data reveal a range of performance among gFOBT variants that allows them to be grouped into low- and high-test sensitivity groups. The specificity of gFOBT also is variable, with low-test sensitivity gFOBT (such as Hemoccult II) tending to have very high specificity and high-test sensitivity gFOBT (such as Hemoccult SENSA) having lower specificity. In a comparison of various stool blood tests, Allison and colleagues observed specificity for cancer and advanced adenomas of 97.7% and 98.1%, respectively, for Hemoccult II, with a combined specificity for cancer and advanced adenomas of 98.1%. For Hemoccult SENSA, which had greater sensitivity for cancer and advanced adenomas compared with Hemoccult II, specificity for cancer and advanced adenomas was 86.7% and 87.5%, respectively, with a combined specificity for cancer and advanced adenomas of 87.5%.[47]

A significant limitation of the potential of testing with gFOBT is that it is commonly performed in the doctor's office as a single-panel test following a digital rectal exam.[39] In a recent national survey of primary care physicians, 31.2% reported using only the in-office method of gFOBT, and an additional 41.2% of physicians reporting using both the in-office method or the take-home method. While this approach may seem pragmatic, Collins et al demonstrated that sensitivity is only 4.9% for advanced neoplasia and only 9% for cancer.[38] The accuracy of this method is so low that it cannot, under any circumstances or rationale of convenience, be endorsed as a method of CRC screening.

An additional limitation observed in the current use of gFOBT is inadequate follow up of a positive test. Despite the fact that all existing CRC screening guidelines recommend colonoscopy follow up of a positive gFOBT, in the same survey that revealed high rates of in-office gFOBT, nearly one-third of physicians reported that they followed up a positive gFOBT with a repeat gFOBT, and a substantial percentage reported that they referred patients to sigmoidoscopy rather than colonoscopy after a positive gFOBT. Similar patterns of testing and responses to positive test results have been reported by patients undergoing at-home screening.[39]

gFOBT—Benefits, Limitations, and Harms. Annual testing with gFOBT has been shown to reduce both CRC mortality and incidence. Testing for occult blood is simple and is associated with minimal harms, although any testing with gFOBT is associated with a possibility of a positive test result that will require follow up with colonoscopy, which is associated with a greater risk of harms. The limitation of gFOBT is that many of the individual tests have limited test sensitivity under the best of circumstances, and this sensitivity may be further compromised by poor and incomplete specimen collection and inadequate or improper processing and interpretation. Program sensitivity (ie, the outcome of repeat annual testing) is considerably higher, but the systems to ensure regular, annual testing often are not in place to support either the patient or his or her physician to be adherent. Further, testing in the office following a digital rectal exam, which is highly inaccurate, has been common and still may persist at significant levels today. When either the test, the testing procedure, or both have very low test sensitivity and when positive tests are not followed up with colonoscopy, the potential is high for patients to have a false sense of reassurance after testing. Finally, patients who choose gFOBT for CRC screening must understand that annual testing is required.

Quality Assurance. If patients and their providers select gFOBT for CRC screening, they should be aware of several quality issues based on programmatic performance in clinical trials. First, the test must be performed properly with 3 stool samples obtained at home. A single-stool sample FOBT collected after digital rectal exam in the office is not an acceptable screening test, and it is not recommended. Prior to testing with a sensitive guaiac-based test, individuals should be instructed to avoid nonsteroidal anti-inflamma-

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tory drugs such as ibuprofen, naproxen, or aspirin (more than one adult aspirin per day) for 7 days prior to testing unless they are on a cardioprotective regimen. There has been debate as to whether additional dietary restrictions reduce compliance with testing and are necessary to reduce the risk of both false-negative and false-positive results. Results of a meta-analysis that examined completion and positivity results found little support for the influence of dietary restrictions on completion or positivity rates, with the exception of completion rates in one study that imposed severe restrictions. However, manufacturers still endorse avoidance of vitamin C in excess of 250 mg from either supplements or citrus fruits and juices and avoidance of red meats (beef, lamb, and liver) for 3 days before testing. This seems prudent since recent consumption of red meat is associated with increased false positivity, and excess vitamin C can result in false-negative results. Second, it is critically important that physician offices and laboratories follow recommended quality-assurance procedures for test development and interpretation. Although rehydration of gFOBT slides increases sensitivity, it is not recommended because it can adversely affect the readability of the test and also substantially increases the false-positive rate. Sinatra and colleagues observed considerable variation in the interpretation of gFOBT among 13 laboratories in Melbourne, Australia, and concluded that ongoing technician training and review of laboratory procedures were important.[50] Better results may be achieved if guaiac-based tests are routinely processed and interpreted in a clinical laboratory. Third, if the test is positive, patients should be advised to have colonoscopy. Repeating the stool test or follow up with noncolonoscopy tests are inappropriate. Fourth, if the test is negative, patients should understand that they need to have repeated testing annually.

gFOBT—Conclusions and Recommendations. Annual screening with high-sensitivity gFOBT (such as Hemoccult SENSA) that have been shown in the published, peer-reviewed literature to detect a majority of prevalent CRC in an asymptomatic population is an acceptable option for colorectal screening in average-risk adults aged 50 years and older. Any positive test should be followed up with colonoscopy. Individuals should be informed that annual testing is necessary to achieve the fullest potential of this test and that they will need follow-up colonoscopy if test results are positive. Screening for CRC with gFOBT in the office following digital rectal exam or as part of a pelvic examination is not recommended and should not be done. Commonly used guaiac tests, with or without rehydration, that have not been shown in the literature to detect a majority of prevalent CRC at the time of testing are no longer recommended.

FIT

The concept of applying an immunochemical method to testing stool for occult blood was first proposed in the 1970s,[51] and commercialization of the technology began in the 1980s. The use of FIT in the United States has lagged behind some other countries, mostly due to the higher costs associated with FIT compared with gFOBT. However, recently increased reimbursement by Medicare made the use of FIT financially viable and has led to its wider acceptability in the United States.[52]

FIT has several technological advantages when compared with gFOBT. FIT detects human globin, a protein that along with heme constitutes human hemoglobin. Thus, FIT is more specific for human blood than guaiac-based tests, which rely on detection of peroxidase in human blood and also react to the peroxidase that is present in dietary constituents such as rare red meat, cruciferous vegetables, and some fruits.[53] Further, unlike gFOBT, FIT is not subject to false-negative results in the presence of high-dose vitamin C supplements, which block the peroxidase reaction. In addition, because globin is degraded by digestive enzymes in the upper gastrointestinal tract, FIT also are more specific for lower gastrointestinal bleeding, thus improving their specificity for CRC. Finally, the sample collection for some variants of FIT are less demanding of patients than gFOBT, requiring fewer samples or less direct handling of stool.

FIT—Efficacy and Test Performance. Recently, a number of new FIT have entered the market, although not all are available in the United States. Some of the new FIT have been evaluated in comparison with gFOBT in diagnostic accuracy studies with human subjects who all undergo

colonoscopy to define the true presence or absence of neoplasia. Other FIT have been evaluated only on the basis of their ability to detect the presence of certain concentrations of blood in laboratory settings. No FIT has been tested in a randomized trial where the outcome of interest is CRC mortality, nor is it likely, as is the case with colonoscopy, that such a study will ever be undertaken.

A number of studies over the past 20 years have compared the diagnostic accuracy of various FIT with gFOBT (most often Hemoccult II or Hemoccult SENSA). In this review, we have focused on studies that compared different FIT with Hemoccult SENSA since at present it has the highest sensitivity of currently marketed gFOBT.[49,54–58] Based on data from these 6 studies, it appears that there are no clear patterns of superior performance in overall test performance between a high-sensitivity guaiac-based test (Hemoccult SENSA) and a variety of FIT.

FIT has been performed in subjects undergoing screening colonoscopy to determine one-time sensitivity and specificity. Morikawa et al studied 21,805 asymptomatic adults who underwent testing with the Magstream 1000 test (not available in the United States), followed by colonoscopy.[59] The Magstream FIT was positive in 5.6% of patients, with 27.1% sensitivity for advanced neoplasia and 65.8% sensitivity for cancer. In a similar study, although not in a totally asymptomatic population, Levi and colleagues sought to measure both sensitivity and specificity of a quantitative FIT and, as well, to measure fecal hemoglobin thresholds most predictive of advanced neoplasia and cancer.[58] One thousand ambulatory patients, some with and some without symptoms of CRC, who were scheduled for colonoscopy and who were willing to also undergo an FIT with 3 samples were included in the study. The hemoglobin content of 3 bowel movements was measured. The sensitivity for cancer with 3 FIT samples with a hemoglobin threshold set at 75 ng/mL was 94.1%. Specificity for cancer was 87.5%. Allison and colleagues recently published results of a comparison of a sensitive gFOBT (Hemoccult SENSA) with a FIT (Hemoccult ICT) for cancer and advanced adenomas in the distal colon in nearly 6,000 average-risk subjects who had undergone FSIG.[49] Both tests showed superior sensitivity for cancer compared with the single-test performance of an unrehydrated gFOBT. The sensitivity for CRC of the FIT and the sensitive gFOBT was 81.8% and 64.3%, respectively. However, the sensitive gFOBT showed superior performance for advanced adenomas (41.3%) compared with FIT (29.5%). Specificity of FIT tends to be higher than that observed for high-sensitivity gFOBT. For example, in the analysis by Allison et al, the specificity of Hemoccult ICT was 96.9% for distal cancer, 97.3% for distal advanced lesions, and 97.5% for all distal advanced neoplasia.[49]

FIT—Benefits, Limitations, and Harms. The spectrum of benefits, limitations, and harms is similar to a gFOBT with high sensitivity. One advantage of FIT over gFOBT appears to be a function of fewer demands on patients undergoing FIT compared with gFOBT. FIT does not require a restricted diet, and the sampling procedures for some forms of FIT are less demanding.[60]

Quality Assurance. If patients and their providers select FIT, they should be aware of several quality issues. Although there are no clinical trials assessing programmatic performance, an effective screening program will depend on repeat testing if the initial test is negative and referral for colonoscopy if the test is positive. At this time, the optimal number of FIT stool samples is not established, but 2 samples may be superior to one.[61]

FIT—Other Issues. Given the lack of clear difference in test performance in studies conducted to date, policy makers, providers, and patients may want to consider other factors when deciding which occult blood test to use. Relevant other factors include cost (both out-of-pocket and total costs) and likelihood of test completion, which appears to be greater with FIT compared with gFOBT.[60]

FIT—Conclusions and Recommendations. Annual screening with FIT that have been shown in the published, peer-reviewed literature to detect a majority of prevalent CRC in an asymptomatic population at the time of testing is an acceptable option for colorectal screening in average-risk adults aged 50 years and older. Any positive test should be followed up with colonoscopy. Adults should be informed that annual testing is necessary to achieve the fullest potential of this test and that they will need follow-up colonoscopy if test results are positive.

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sDNA

Knowledge of molecular genomics provides the basis of a new method of CRC screening that tests stool for the presence of known DNA alterations in the adenoma-carcinoma sequence of colorectal carcinogenesis. Adenoma and carcinoma cells that contain altered DNA are continuously shed into the large bowel lumen and passed in the feces. Because DNA is stable in stool, it can be differentiated and isolated from bacterial DNA found in the feces.[62] No single gene mutation is present in cells shed by every adenoma or cancer. Thus, a multitarget DNA stool assay is required to achieve adequate sensitivity. At present there is only one commercially available sDNA test. The prototype assay of this test (version 1.0) for which most of the published evidence is available consisted of a multiple-marker panel that included 21 separate point mutations in the *K-ras, APC, P53* genes; a probe for *BAT-26* (a marker of microsatellite instability); and a marker of DNA integrity analysis (DIA). The sDNA that is currently commercially available is a second-generation version of this test (version 1.1) that includes this same marker panel but incorporates several technical advances related to processing and specimen preservation.[63,64] Whereas gFOBT and FIT test a sample of stool or sample of water surrounding stool, the currently available sDNA test requires the entire stool specimen (30 g minimum to ensure an adequate sample of stool for evaluation). Collection kits have been designed to facilitate specimen collection and mailing and to enhance compliance.

sDNA—Efficacy and Test Performance. Several studies on the sensitivity and specificity of sDNA testing for CRC detection have been published utilizing a panel of DNA markers.[37,65–69] Test sensitivity for CRC in these studies ranged from 52% to 91%, with specificity ranging from 93% to 97%. Lower sensitivity in some of these studies has been attributed to suboptimal sensitivity performance of DIA resulting from DNA degradation during transit of specimens to the laboratory. The changes associated with version 1.1 are reported to address these problems. One study utilizing version 1.1 has been published by Whitney et al[63] reporting a sensitivity for CRC of 70%.

sDNA has been compared to a low-sensitivity gFOBT in one large, prospective study of an average-risk screening cohort. Imperiale et al conducted an investigation in a cohort of 2,507 average-risk individuals undergoing colorectal neoplasia screening by 3 modalities: sDNA using the prototype assay (version 1.0), gFOBT (nonrehydrated Hemoccult II), and colonoscopy.[37] sDNA testing had statistically significantly better sensitivity for CRC compared with Hemoccult II (52% versus 13%) and for all cancers and high-grade dysplasia (40.8% versus 14.1%), with comparable specificity. In this study, sDNA was much less sensitive in the detection of all advanced adenomas (15.1%), defined as a tubular adenoma at least 1 cm in diameter, an adenoma with a villous histologic appearance, or an adenoma with high-grade dysplasia, although it still showed superior performance to the comparison gFOBT (10.7%).[37] Data on program performance of sDNA screening are lacking. Information on the sensitivity and specificity of CRC and adenoma detection comes from an evaluation of results from a single test. Also, the currently available sDNA gene test—version 1.1—has not been rigorously tested in screening cohorts but based on available data can be reasonably assumed to perform as well or better than version 1.0.[63] New version assays with better DNA stabilization and simplified genetic analyses may be more sensitive than version 1.0 but require testing in screening cohorts.[70]

sDNA—Benefits, Limitations, and Harms. The primary benefit of sDNA is that this methodology has acceptable sensitivity for CRC and is built upon the concept of detecting molecular markers associated with advanced colorectal neoplasia. It is not dependent on the detection of occult bleeding, which is intermittent and nonspecific, and it requires only a single stool collection. Further, newer versions may have better sensitivity as more is learned about markers that are common across all prevalent CRC, as well as advanced adenomas. sDNA sampling also is noninvasive and lacks physical harm. Patient and provider acceptance of this technique appears to be high, with available data indicating that sDNA is preferred over other tests by some individuals, and among others testing with sDNA, it is at least as acceptable to patients as testing with gFOBT.[29,71] Berger et al reported that most individuals undergoing sDNA who completed a mailed survey reported

satisfaction with the sDNA testing process, and most reported that they would repeat testing if recommended by their physician.[72]

A clear limitation of sDNA testing for the detection of CRC and large adenomas is that test sensitivity is based on a panel of markers that appears to identify the majority of but not all CRC. Further, it is not known what proportion of advanced adenomas is identified with the current commercial version (version 1.1) of the sDNA test. Other potential limitations that have considerable implications for cost-effectiveness are the unit cost of the current test,[73] which is much higher than the other stool tests, and the frequency with which the test should be performed, which is uncertain. Currently, the test is under review by the Food and Drug Administration for 510K certification but is commercially available under the "home brew" category.

An additional issue is the clinical relevance of a positive genetic test without identification of the cause of the abnormality; this has not been studied systematically. At issue for a test that is based on molecular markers is the degree to which a positive test, with no evidence of advanced lesions upon completion of colonoscopy, is truly negative or positive for a lesion that is not yet clinically evident. Osborn and Ahlquist have highlighted the fact that inasmuch as cancers exfoliate cells and that these cells can survive the digestive process and ultimately be excreted in stool, high prevalence supracolonic aerodigestive cancers may also be detected by sDNA.[74] However, at this time, the significance of a positive test result in a patient with a negative follow-up evaluation is unknown.

Quality Assurance. Individuals should be informed about the benefits and limitations of screening for CRC with sDNA, including the facts that at present the test is more sensitive for cancer than advanced adenomas, that the current panel of markers will not identify all cancers, and that a positive test will need to be followed up with colonoscopy. Individuals should also know that the rescreening interval after a negative test is uncertain. Individuals should be made aware that their stool specimen must be packaged and shipped in a customized collection kit that includes a specially designed ice pack. Patients must have access to a working freezer and allow this ice pack to freeze for at least 8 hours prior to use. If the specimen is returned without the ice pack or if there are unforeseen delays in specimen return or processing, the specimen may be rejected.

sDNA—Other Issues. Testing stool for mutated DNA and other markers poses unique challenges in shared decision making. The panel of markers that was evaluated in population studies was not sensitive for all advanced lesions and cancer, and there is uncertainty about improvements in the sensitivity of newer versions for advanced neoplasia and cancer in screening cohorts. At this time, patients will need to be informed that sDNA will detect some but not all advanced lesions and cancers. There also is uncertainty about how positive results without evidence of advanced lesions or cancer on follow up should be interpreted by patients and whether or not these patients require a different plan for ongoing surveillance.[75] Additional research is necessary to resolve these questions.

As noted previously, the most informative data on the performance of sDNA is from version 1.0, which has been replaced with version 1.1; the newer version uses the same panel of markers but is reported to have improved quality.[63,70] Newer versions are currently under evaluation and are reported to have improved sensitivity, with diminution of specificity. The evolution of tests of this type raises important questions as to how performance of successive iterations should be evaluated and whether large prospective studies of asymptomatic patients with follow-up colonoscopy among all participants are required. Another question worthy of consideration is whether or not including a sensitive gFOBT or FIT at the time of testing would improve sensitivity, without adversely affecting specificity. In a recent retrospective analysis of stool samples from patients with CRC and donor controls, combined results from a standard gFOBT and a panel of DNA markers (*APC*, *BAT-26*, and *L-DNA*) resulted in a combined sensitivity for cancer of 93% and specificity of 89%.[76]

sDNA—Conclusions and Recommendations. In previous assessments of the performance of sDNA, both the ACS and the USMSTF concluded that data were insufficient to recommend screening with sDNA for average-risk individuals.[19,24] Based

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on the accumulation of evidence since the last update of these guidelines, the panel concluded that there now are sufficient data to include sDNA as an acceptable option for CRC screening. As noted above, testing stool for molecular markers is an evolving technology. New iterations of these tests, either technological enhancements of existing tests or completely new test variants, should be carefully evaluated in order to determine that they meet the criteria of detecting a majority of cancers at the time of screening but also have acceptable performance in a screening cohort. While the manufacturer of the one test that is commercially available currently is recommending a 5-year interval for routine screening between examinations with normal results, the panel concluded that there were insufficient data upon which to endorse this interval. Such an interval was judged by the committee to be appropriate only for a test that has very high sensitivity for both cancer and adenomatous polyps—a standard that has not been documented for sDNA to date. At this time, further research is needed to determine the interval between negative sDNA exams. Based on current evidence, the appropriate interval is uncertain.

TESTS FOR THE DETECTION OF ADENOMAS AND CRC

Endoscopy Examinations of the Colon and Rectum—FSIG and Colonoscopy

FSIG

FSIG is an endoscopic procedure that examines the lower half of the colon lumen. In addition to the standard 60 cm sigmoidoscope, the exam may be performed with a variety of endoscopic instruments, including a colonoscope, an upper endoscope, and a pediatric colonoscope. It is typically performed without sedation and with a more limited bowel preparation than standard colonoscopy. Since sedation is not required, it can be performed in office-based settings and by nonphysicians, including nurses or physician assistants, provided adequate training has been received.[77]

FSIG—Efficacy and Test Performance. The use of FSIG for CRC screening is supported by high-quality case-control and cohort studies, which have been reviewed in detail elsewhere.[24] In 2 well-known case-control studies, FSIG was associated with a 60% to 80% reduction in CRC mortality for the area of the colon within its reach, and this protective effect appears to persist for 10 years or more.[4,78] A small, randomized trial[79] and a case-control study[80] also demonstrated decreased CRC incidence in the sigmoidoscopy-screened group compared with a nonscreened control group. There are 4 prospective, randomized controlled trials ongoing in the United States and Europe,[81–84] and results are expected in the near future.

Additional evidence supporting the effectiveness of FSIG derives from colonoscopy studies. FSIG is 60% to 70% as sensitive for advanced adenomas and cancers in the colon compared with colonoscopy.[85,86] However, this figure varies according to age, with proximal neoplasia becoming more common after age 65 years.[87] Due to observed differences in the distribution of colonic neoplasia, FSIG may also be less sensitive in women than in men,[88] although the overall prevalence of advanced colonic neoplasia is lower in women than in men,[89] and it may be less sensitive in African Americans than in Whites. Several studies have indicated that African Americans have a higher prevalence of proximal lesions than Whites,[90,91] although a more recent evaluation of proximal lesions in a consecutive series of African American and White adults undergoing FSIG did not observe a statistically significant difference in proximal lesions between the 2 groups based among those adults with neoplastic lesions identified during sigmoidoscopy.[92] In addition, a number of recent studies have documented a lower prevalence of distal colon and rectal lesions in Whites compared with Hispanics and Asians.[92,93] Differences in the prevalence of distal and proximal lesions based on age, gender and ethnicity, and the benefits and limitations of CRC screening with FSIG among these different groups remain important areas for continued investigation.

The effectiveness of sigmoidoscopy depends on the completion of a high-quality exam. Studies have demonstrated variable adenoma detection rates at screening sigmoidoscopy that are attributed to exam quality and completeness.[94] Advanced neoplasia has been found within 3 years of a negative sigmoidoscopy in the Prostate,

Lung, Colorectal and Ovarian Cancer Screening Trial, raising issues of exam quality.[95] Although scope insertion to beyond 40 cm is only one measure of quality, the clinical studies that report adenoma detection and efficacy all achieve this level of insertion.[96] Studies have demonstrated that deeper levels of insertion are associated with a higher detection rate for advanced neoplasia.[86] Therefore, the panel recommends that if sigmoidoscopy is performed for CRC screening, insertion to 40 cm or beyond is required.

Exam quality also depends on the appropriate management of endoscopic findings. The panel recommends that any endoscopist performing sigmoidoscopy should be skilled in obtaining biopsies of polyps to determine histology. The histologic findings are informative for follow-up decision making. There is evidence from 2 large screening studies that if a patient has an adenoma of any size in the distal colon, he or she has an increased risk of proximal advanced neoplasia (2-fold or higher) compared with patients who have no polyps or only hyperplastic polyps in the distal colon.[14,85] Therefore, we recommend that most patients who have adenomas discovered at sigmoidoscopy should undergo colonoscopy. If biopsies are not obtained, another strategy is to refer all patients with one or more polyps >5 mm for colonoscopy.[97]

The appropriate interval between normal sigmoidoscopy exams is uncertain and may extend to 10 years, although the protective effect would depend greatly on the quality of the examination. Prior ACS and USMSTF CRC screening guidelines have recommended a 5-year interval between normal FSIG examinations, while recommending a 10-year interval between colonoscopy examinations.[18,24] The shorter interval was recommended for FSIG because of concerns about exam quality and completeness in most clinical settings. In settings where an experienced endoscopist performs a complete examination on a well-prepared patient and achieves insertion beyond 40 cm, a 10-year interval between screening FSIG may be justified. Since, these criteria are not routinely achieved in many clinical settings, a 5-year rescreening interval remains the standard recommendation.

The most important limitation in the evidence for FSIG is the lack of a longitudinal head-to-head comparison between FSIG screening and other CRC screening tests, such as colonoscopy or the different stool blood tests. Apart from the issue of patient preference, a key question for screening policy is the incremental benefit of colonoscopy over FSIG, given the higher direct medical and indirect costs of colonoscopy and the higher risk of complications with colonoscopy.[98]

FSIG—Benefits, Limitations, and Harms. The chief advantage of FSIG is that it can be performed with a simple preparation (2 Fleet enemas), without sedation, and by a variety of examiners in diverse settings. With respect to distal bowel cleansing, the use of enemas is often imperfect, and superior bowel cleansing is achieved with the more thorough oral sodium phosphate procedure. Patients have reported a more favorable experience with the oral prep compared with the enemas.[99] The absence of sedation is perceived by some patients as an advantage and by others as a disadvantage, although in one series, a greater percentage of patients undergoing sigmoidoscopy reported periprocedural discomfort (during and postexam) compared with patients undergoing colonoscopy.[100] Moreover, lack of sedation is associated with greater patient discomfort and greater patient reluctance to undergo the examination for future screening.[100]

An additional limitation of FSIG is that there may be considerable variation both in depth of insertion of the scope and in adenoma detection at FSIG between different examiners,[94,101] and this may reduce the effectiveness of FSIG for CRC screening, especially in practice settings of low volume. Quality assurance is an important issue for flexible sigmoidoscopists and has been reviewed in detail elsewhere.[77] Providers should be well trained and should exceed the published American Society for Gastrointestinal Endoscopy standards for a minimum number of training examinations prior to performing sigmoidoscopy without supervision.

The chief limitation of FSIG is that it does not examine the entire colon but, under optimal conditions, only the rectum, sigmoid, and descending colon. However, several lines of evidence support the idea that the incremental benefit of colonoscopy is less than simply the difference in sensitivity for advanced adenomas between

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colonoscopy and FSIG because many patients with small distal adenomas will receive colonoscopy, which may result in discovery of proximal advanced adenomas and cancer. The complications of FSIG include colonic perforation, even if no biopsy or polypectomy is performed, but this occurs in fewer than one in 20,000 examinations.[81,102]

Quality Assurance. Quality indicators for FSIG have been previously published.[77] Key elements include (1) appropriate training of endoscopists; (2) satisfactory examination rates to beyond 40 cm; (3) expected adenoma detection rates based on age and gender; and (4) ability to biopsy suspected adenomas. The effectiveness of an FSIG program is based on the assumption that if an adenoma is detected in the sigmoid colon or rectum, the patient would be referred for total colonoscopy. Patients should fully understand that in most circumstances colonoscopy will be recommended if an adenoma is detected during FSIG and that if they are unwilling to accept referral to colonoscopy, they should have a different form of screening.

FSIG—Other Issues. FSIG use in the United States has been decreasing in the recent decade, coincident with a rise in colonoscopy usage. An analysis of Medicare data from the years 1993 to 2002 demonstrated a 54% decrease in sigmoidoscopy use between the earliest and latest periods studied and a more than 6-fold increase in colonoscopy usage over the same time frame.[103] Other data from endoscopic facilities across the United States collected and analyzed by investigators from the Centers for Disease Control and Prevention estimated that approximately 2.8 million FSIG examinations and 14.2 million colonoscopy examinations were performed in 2002.[104] Low reimbursement and a shortage of adequately trained examiners are 2 barriers to the availability of FSIG.[30,105] In settings where reimbursement rates have not been a concern and where nurse endoscopists have been employed, high rates of FSIG utilization have been achieved.[106]

FSIG—Conclusion and Recommendations. FSIG can result in the identification of the majority of prevalent CRC at the time of screening, when the examination reaches the splenic flexure or beyond 40 cm as a reasonable target for insertion and when adenomas in the distal colon are used as an indication for the need for colonoscopy. Although the appropriate interval between normal examinations is uncertain, FSIG is recommended to be performed for screening every 5 years in most clinical settings due to concerns about exam quality and completeness. FSIG can be performed alone, or consideration can be given to combining FSIG performed every 5 years with a highly sensitive gFOBT or FIT performed annually. In high-quality centers (such as the program operated by Kaiser Permanente in California) where procedures are conducted by properly trained and experienced endoscopists who document regular insertion beyond 40 cm with a good bowel preparation, a 10-year interval between negative exams may be reasonable.

Individuals should be informed about the limitations of FSIG, including the fact that it examines only the distal colon; that there is a risk, albeit small, of perforation; and that they may experience discomfort during and after the examination. Patients should also understand that the examination achieves higher quality when bowel cleansing follows the same protocol as that for colonoscopy. Finally, patients should be informed that positive test findings will need to be followed up with colonoscopy.

Colonoscopy

Colonoscopy is one of the most commonly performed medical procedures in the United States, with estimates of up to 14 million procedures performed in 2003.[104] Colonoscopy allows direct mucosal inspection of the entire colon from the appendiceal orifice to the dentate line and same-session biopsy sampling or definitive treatment by polypectomy in the case of precancerous polyps and some early-stage cancers.

The modern colonoscope is capable of examining the entire bowel, with the examination terminating at the cecum. Patients generally adopt a liquid diet one or more days before the examination, followed by either ingestion of oral lavage solutions or saline laxatives to stimulate bowel movements until the bowel is clean. Proper bowel preparation is a critical element in the accuracy and cost-effectiveness of screening with colonoscopy.[107] It is common for the patient to receive a mild sedative prior to the procedure, but

it is not essential for those who tolerate the procedure with only mild discomfort.[108]

Colonoscopy—Efficacy and Test Performance. There are no prospective randomized controlled trials of screening colonoscopy for the reduction in incidence or mortality of CRC; however, because colonoscopy is used to evaluate other positive screening tests, there is evidence to indicate that colonoscopy and polypectomy result in incidence reductions in randomized controlled trials of other screening tests. The University of Minnesota randomized controlled trial of FOBT observed a 20% reduction in incidence of CRC, which the authors attribute to colonoscopy and polypectomy in patients with a positive FOBT.[7] In a randomized controlled trial of FSIG versus no screening and with follow-up colonoscopy and polypectomy performed for any polyp detected at sigmoidoscopy, the screening group experienced an 80% incidence reduction in CRC.[79]

Case-control studies cited above of sigmoidoscopy and polypectomy in screening populations also are considered to provide supporting evidence for colonoscopy because of the similarity of the examinations in the distal colon. In a case-control study of colonoscopy in the US VA population, colonoscopy in symptomatic patients was associated with a 50% reduction in mortality.[109]

The evaluation of incidence rates of CRC in adenoma cohorts after baseline colonoscopy and polypectomy is another form of evidence commonly cited to support colonoscopy for CRC screening. In the National Polyp Study, the incidence of CRC after clearing colonoscopy was reduced by 76% to 90% compared with 3 nonconcurrent reference populations.[110] In an Italian adenoma cohort study with removal of at least one adenoma ≥5 mm, there was an 80% reduction in CRC incidence compared with expected incidence in a reference population.[111] However, not all studies have shown the same level of protection. Combined data from 3 US chemoprevention trials showed incidence rates of CRC after clearing colonoscopy approximately 4 times that seen in the National Polyp Study, with no reduction in CRC incidence compared with data from the Surveillance Epidemiology and End Results (SEER) database in the United States,[112] and 2 US dietary intervention trials also showed higher rates of incident CRC after clearing colonoscopy than were observed in the National Polyp Study.[113,114] These differences may reflect exclusion of patients with sessile adenomas >3 cm in size in the National Polyp Study, more effective baseline clearing (13% of patients in the National Polyp Study had 2 or more baseline colonoscopy to complete clearing), or unmeasured differences in the average quality of colonoscopy between the studies.

Overall, the data support the conclusion that colonoscopy with clearing of neoplasms by polypectomy has a significant impact on CRC incidence and, thus, by extension, mortality. The magnitude of the protective impact is uncertain; it is not absolute, nor are apparent failures well understood. In a study of 35,000 symptomatic patients in Manitoba who had undergone a negative colonoscopy and who then were followed for 10 years, the investigators observed significant reductions in CRC incidence over time, but the incidence reductions were less than 50% for each of the first 5 years and no more than 72% by 10 years. These findings suggest detection failures during the initial, apparently normal, colonoscopy.

Colonoscopy—Benefits, Limitations, and Harms. A principal benefit of colonoscopy is that it allows for a full structural examination of the colon and rectum in a single session and for the detection of colorectal polyps and cancers accompanied by biopsy or polypectomy. All other forms of screening, if positive, require colonoscopy as a second procedure.

Patient surveys indicate that patients willing to undergo invasive testing tend to choose colonoscopy as their preferred test.[71] In addition to being a complete examination of the colon, individuals may also regard sedation during the procedure as an advantage. Patients in the same practice who had undergone unsedated FSIG screening were more than twice as likely to say that they would not return for additional screening compared with those who had undergone colonoscopy with sedation.[100]

Colonoscopy has several limitations. It requires one or more days of dietary preparation and bowel cleansing, usually a day dedicated to the examination, and because of sedation, a chaperone is needed for transportation. It is an invasive

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procedure, and surveys indicate that a significant percentage of adults prefer other noninvasive options for CRC screening.[71,115,116] Effective performance of the procedure is dependent on thorough bowel preparation, which is often perceived as the most unpleasant part of the colonoscopy process by those who have undergone the test. Limitations with regard to detection of neoplasia have been previously discussed, and the fact that colonoscopy is operator-skill dependent is another significant limitation. Patients are generally poorly informed about the problem of variable performance of the procedure and are unaware of the skill level of their endoscopists. Formal quality-assurance programs do not exist, and the current reimbursement system for colonoscopy does not reward careful examination but tends to reward rapidly performed examinations and repeated examinations at unnecessarily short intervals.[117] Polypectomy is sometimes ineffective in eradicating polyps, a factor that has been implicated as the cause of up to 25% of interval cancers.[118,119] Finally, colonoscopy is not an infallible "gold standard." Controlled studies have shown the colonoscopy miss rate for large adenomas (=10 mm) to be 6% to 12%.[120,121] The reported colonoscopy miss rate for cancer is about 5%.[120,122]

Colonoscopy can result in significant harms, most often associated with polypectomy, and the most common serious complication is postpolypectomy bleeding. The risk of postpolypectomy bleeding is increased with large polyp size and proximal colon location; however, small polyp bleeds are more numerous than large polyp bleeds because small polyps are so numerous. Another significant risk associated with colonoscopy is perforation. Perforation increases with increasing age and the presence of diverticular disease and was recently estimated to occur in 1 in 500 of a Medicare population and approximately 1 in 1,000 screened patients overall.[123] Because of the age effect, perforation rates measured in the Medicare population may overestimate the overall risk of perforation in colonoscopy; however, a large study in the Northern California Kaiser Permanente population also identified a perforation rate of 1 in 1,000.[98] In addition, cardiopulmonary complications such as cardiac arrhythmias, hypotension, and oxygen desaturation may occur, although these events rarely result in hospitalization. Cardiopulmonary complications represent about one-half of all adverse events that occur during colonoscopy and usually are related to sedation.[124] Thus, while screening colonoscopy has established benefits with regard to the detection of adenomas and cancer, complications related to colonoscopy are a significant public health challenge.

Quality Assurance. Recent publications have highlighted criteria for best practices and important quality indicators for colonoscopy.[124–126] High-quality colonoscopy depends on (1) appropriate training and experience; (2) proper documentation of risk assessment; (3) complete exam to the cecum with adequate mucosal visualization and bowel preparation; (4) ability to detect and remove polyps safely; (5) documentation of polypoid lesions and methods of removal; (6) timely and appropriate management of adverse events; (7) appropriate follow up of histopathology findings; and (8) appropriate recommendation for surveillance or repeat screening based on published guidelines. Although colonoscopy is commonly used for screening, diagnosis, and therapy, until recently there was no standardized reporting system for this procedure. To enhance clear communication about colonoscopy findings between health care professionals and to facilitate quality-improvement programs, the Quality Assurance Task Group of the National Colorectal Cancer Roundtable developed a reporting and data system for colonoscopy based on previously published continuous quality-improvement indicators.[126]

Colonoscopy—Other Issues. Colonoscopy in the United States is performed by the overwhelming majority of gastroenterologists, most colorectal surgeons, many general surgeons, and a small percentage of primary care physicians. Colonoscopy volumes have risen steadily in the United States, while volumes for FSIG and DCBE have declined substantially in the past decade, and FOBT has remained relatively stable, although a small decline in the rate was observed among women.[8,127] Colonoscopy is offered in the vast majority of American hospitals and is also widely performed in ambulatory surgery centers and in physicians' offices in some parts of the country. A recent survey of American colonoscopists suggested that capacity could be increased from the present 14

million annual procedures to 22 million with currently available resources,[104] although the methodology behind this estimate has been criticized,[128] and other estimates of capacity are less optimistic regarding capacity.[129,130] In the short term, colonoscopy capacity appears sufficient to handle slow increases in demand for the majority of the US population, although the capacity to handle a sharp increase in demand for screening or diagnostic/therapeutic colonoscopy overall is uncertain and likely highly variable geographically.

Some of the limitations in the availability of colonoscopy for screening potentially could be overcome by more appropriate use of surveillance colonoscopy after polyp resection, which has been shown to be excessive among gastroenterologists and particularly among general surgeons and primary care physicians.[117,131] Excessive rates of short-term follow up after polypectomy, especially for small lesions, also likely diminish the cost-effectiveness of colonoscopy. For these reasons, the ACS and USMSTF recently updated and further clarified recommendations for post-polypectomy surveillance.[25] The case against serial short-term follow-up strategies rests on observations that over the short term, the risk of significant growth of adenomas is quite low. However, because there is uncertainty about the natural history of small colorectal adenomas and perhaps because of a desire to err on the side of prudence, a significant percentage of clinicians recommends follow-up intervals that are considerably shorter than recommended, and surveillance intervals often are not adjusted for subsequent negative findings.[117] Recent guideline recommendations continue to expand the interval between follow-up colonoscopy examinations in patients with low-risk adenomas.[26]

Colonoscopy—Conclusions and Recommendations. The evidence base to support screening colonoscopy, though indirect, is substantial. The appropriate interval between negative colonoscopy screening exams is uncertain because of lack of long-term follow-up data. At present, colonoscopy every 10 years is an acceptable option for CRC screening in average-risk adults beginning at age 50 years. Individuals should be informed about the limitations of colonoscopy, including the fact that it may miss some cancers and significant adenomas and that there is a risk, albeit small, of perforation, hemorrhage (following polypectomy), subsequent hospitalization, and in very rare circumstances, more serious harms. A full bowel cleansing is necessary prior to colonoscopy. Sedation usually is used to minimize discomfort during the examination, and thus a chaperone is required to provide transportation after the examination.

Imaging Examinations of the Colon and Rectum—DCBE and Computed Tomography

DCBE

The DCBE, sometimes referred to as air-contrast barium enema, evaluates the colon in its entirety by coating the mucosal surface with high-density barium and distending the colon with air introduced through a flexible catheter that is inserted into the rectum. Multiple radiographs are acquired while varying the patient position during direct fluoroscopic evaluation and, subsequently, with conventional radiographic equipment. Colonic preparation, usually a 24-hour dietary and laxative regimen, is essential for an optimal examination. Sedation is not utilized, and the duration of the procedure averages about 20 to 40 minutes. Patients may experience mild to moderate discomfort during and after the procedure, but a prompt return to normal activity is typical.

DCBE was contemporaneously adopted as a CRC screening option by the Multi-Society Gastroenterology Consortium and the ACS in 1997 and has continued to be included among the recommended screening options in periodic updates of those guidelines,[12,17,24,132] as well as those of the US Preventive Services Task Force.[21] It is also considered appropriate for screening by the ACR.[133] CRC screening of the average-risk population with DCBE also has been a designated Medicare benefit since 1997.[134]

DCBE—Efficacy and Test Performance. There have been no randomized controlled trials evaluating the efficacy of DCBE as a primary screening modality to reduce incidence or mortality from CRC in average-risk adults, and there also are no case-control studies evaluating the performance of DCBE. Further, the existing literature describing the test performance of DCBE also is limited by study designs that are retro-

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spective and commonly do not report findings from an asymptomatic or average-risk population.[135,136] In some reports, asymptomatic individuals were selected for investigation during neoplasm surveillance or after a prior screening test (eg, FSIG or FOBT). Finally, similar to the literature related to other CRC screening technologies, the DCBE literature varies considerably in terms of measurement and outcome metrics (ie, polyps, cancers, all neoplasms, adenomas, size categorizations, etc.), and these measurements may be estimated by lesion or by population.

Most studies evaluating the cancer-detection capability of DCBE utilized a methodology in which all patients in an institution- or population-based database that had been diagnosed with CRC were assessed for a history of a prior DCBE within a defined time frame, the length of which was not consistent between studies but usually ranged from 2 to 5 years. The assumption was that missed cancers on DCBE would subsequently be clinically detected. The majority of these studies showed sensitivity for cancer of 85% to 97%.[137–150]

Review of the literature concerning the performance of DCBE for polyps is more difficult due to the described biases and heterogeneity of study design; in particular, the target lesion and thresholds considered clinically significant often varied based upon size and/or morphology. Two studies involving truly asymptomatic individuals were performed in surveillance groups with a history of prior adenoma removal.[151,152] These demonstrated sensitivities of 48% (N = 23) for adenomas ≥1 cm and 73% (N = 56) for adenomas >7 mm, respectively. It should be noted that in the former study, the DCBE detected 75% (6 of 8) with advanced histology.[153]

DCBE—Benefits, Limitations, and Harms. The potential benefits derived from the DCBE are that it evaluates the entire colon in almost all cases and can detect most cancers and the majority of significant polyps. DCBE also provides an opportunity for a full structural examination for individuals for whom colonoscopy has either failed or is contraindicated.

DCBE has several limitations. The acceptability of DCBE may be limited by the requirement for extensive colonic preparation, and some patients experience discomfort during and after the procedure. Suboptimal preparation can reduce both sensitivity and specificity. Further, there is no opportunity for biopsy or polypectomy, and any individual with findings of polyps ≥6 mm on DCBE should undergo colonoscopy. The lower sensitivity for significant adenomas when compared with colonoscopy may result in less favorable outcomes regarding morbidity and mortality from CRC. DCBE is also limited by the operator dependence of the radiologist or technologist performing the examination, as well as by the radiologist interpreting the examination. DCBE is a relatively safe procedure with a lower perforation rate when compared with colonoscopy (1 of 25,000 versus 1 of 1,000 to 2,000).[154]

Quality Assurance. The DCBE is a full structural examination of the entire colon that can be performed by radiologists or radiology residents and trained technicians under the supervision of a radiologist. Factors that can affect the quality of the DCBE examination include (1) ability to fully evaluate the entire colon due to lack of retained barium or collapse of segments of the colon; (2) adequacy of the bowel preparation; (3) patient's ability to stand and be imaged in prone and supine positions; and (4) reader's experience in interpretation. Caution is advised when performing a DCBE on the same day after polypectomy to avoid a perforation. The ACR has published guidelines that detail the basic requisites for a high-quality examination,[155] as well as a quality-assurance manual for the DCBE.[155] Interaction with referring physicians to correlate radiologic findings with endoscopic and/or surgical outcomes may also be an effective ongoing quality assurance in clinical practice.

DCBE—Other Issues. It is likely that the decline in the use of DCBE for CRC screening in average-risk adults will continue.[156–158] This decline in the utilization of DCBE has had an impact on training programs, as radiology residents have had less opportunity to develop the necessary skills to perform the procedure properly. Moreover, although there likely are sufficient numbers of radiologists in clinical practice who are available currently to perform DCBE studies, there has been a decline in radiologists' enthusiasm for the DCBE due to its labor-intensive nature, the low reimbursement rate, and greater interest in newer and more complex

technologies such as computed tomography (CT) and magnetic resonance imaging (MRI). Based on these trends, it is likely that in the next 5 years, that there will be even fewer radiologists adequately trained to perform this procedure due to the low volume of DCBE studies currently being requested, as well as low professional interest. At present, the DCBE remains an option for direct imaging of the entire colon and may be of particular value where colonoscopy resources are limited or colonoscopy is contraindicated or less likely to be successful (eg, prior incomplete colonoscopy, prior pelvic surgery, etc.).

DCBE—Conclusions and Recommendations. DCBE every 5 years is an acceptable option for CRC screening in average-risk adults aged 50 years and older. Discussions with patients should include a description of the test characteristics, the importance of adherence to a thorough colon cleansing, test accuracy, the likelihood of a positive test, and the need for subsequent colonoscopy if the test is abnormal. The choice of DCBE for screening can be made on an individual basis, depending on factors such as personal preference, cost, and the local availability of trained radiologists able to offer a high-quality examination.

CTC

CTC, also referred to as virtual colonoscopy, is a minimally invasive imaging examination of the entire colon and rectum. CTC uses CT to acquire images and advanced 2-dimensional (2D)- and 3-dimensional (3D)-image display techniques for interpretation. Since its introduction in the mid-1990s, there have been rapid advancements in CTC technology. Multidetector CT now permits image acquisition of thin 1 to 2 mm slices of the entire large intestine well within breath-hold imaging times. Computer imaging graphics allow for visualization of 3D endoscopic flight paths through the inside of the colon, which are simultaneously viewed with interactive 2D images. The integrated use of the 3D and 2D techniques allows for ease of polyp detection, as well as characterization of lesion density and location. The 2D images also allow for limited evaluation of the extracolonic structures.

Adequate bowel preparation and gaseous distention of the colon are essential to ensure a successful examination. Patients typically undergo full cathartic preparation along with a clear liquid diet the day before the study, similar to the requirements for colonoscopy. Tagging of residual solid stool and fluid with barium and/or iodine oral contrast agents is being increasingly used and validated in large trials. At CT, a small-caliber rectal catheter is inserted into the rectum, followed by automated or manual insufflation of room air or carbon dioxide. Intravenous contrast generally is not given to patients undergoing screening but can be helpful in some patients with more advanced symptoms. Typically, the entire procedure on the CT table takes approximately 10 minutes, with no sedation or recovery time needed. Research into noncathartic approaches to minimize the bowel preparation is underway, but this technique has not yet been validated in a multicenter screening trial.[159–161] However, under conditions where same-day or next-day referral for colonoscopy would be possible, one drawback of noncathartic CTC is that a cathartic bowel preparation would still be required prior to removal of polyps.

CTC—Efficacy and Test Performance. No prospective, randomized, controlled clinical trial has been initiated (nor is one planned) to directly demonstrate the efficacy of CTC in reducing mortality from CRC. Given the cumulative body of evidence in support of CRC screening for reducing mortality and the value of polypectomy in reducing incidence, studies of CTC have focused on the detection of advanced neoplasia.

The test performance characteristics of CTC for polyp detection are derived by using optical colonoscopy (OC) as the reference standard. Early single-center CTC clinical trials involving small, polyp-rich cohorts[162–164] provided encouraging initial results and served as proof of concept that paved the way for larger multicenter screening trials. Two early trials by Cotton et al[165] and Rocky et al[166] included approximately 600 subjects each and observed per-patient sensitivity for large polyps of 55% and 59%, respectively. However, these 2 studies did not evaluate screening in an asymptomatic population, nor did they apply the latest CTC techniques. A more recently initiated multi-institutional screening trial using more advanced CTC techniques demonstrated more favorable performance. Pickhardt et al studied

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1,233 asymptomatic adults and introduced the techniques of stool tagging and primary 3D polyp detection, neither of which were used in the 2 earlier multi-institutional trials.[167] This trial reported a 94% sensitivity for large adenomas, with a per-patient sensitivity for adenomas ≥6 mm of 89%.

In 2005, 2 meta-analyses reviewed the cumulative published CTC performance data, including both high-risk and screening cohorts, with one analysis representing 33 studies on 6,393 patients.[168,169] On a per-patient basis, pooled CTC sensitivity and specificity for large (≥10 mm) polyps was found to be 85% to 93% and 97%, respectively. Pooled sensitivity and specificity for detection of small polyps (6 to 9 mm) was 70% to 86% and 86% to 93%, respectively. Of note, the pooled CTC sensitivity for invasive CRC was 96%,[168] comparable with the reported sensitivity for OC.[119,121]

There also are a number of CTC trials currently in progress within the United States and Europe. Initial results from smaller screening trials utilizing 3D polyp detection by Cash et al[170] and Graser et al[171] have shown CTC performance characteristics similar to that of Pickhardt et al, providing at least a measure of independent validation for this screening technique. Also of particular interest is the recently completed ACRIN Study 6664: National CT Colonography Trial, which is sponsored and funded by the National Cancer Institute. The primary aim of this trial was to assess CTC performance for large adenomas and advanced neoplasia in a large screening cohort of 2,500 patients across 15 institutions. State-of-the-art techniques included oral contrast tagging, colonic distention with automated carbon dioxide delivery, multidetector row CT (≥16 slice) with thin collimation, and both 2D and 3D polyp detection on dedicated CTC software systems. Specialized training and achievement of a high level of expertise were required of the radiologists prior to participation in the study. Preliminary findings announced at the 2007 annual meeting of ACRIN on September 28, 2007, were consistent with other recent studies using state-of-the-art techniques.

Beyond validation, a recent study demonstrated the efficacy of CTC to select patients who would benefit from therapeutic polypectomy. Kim et al recently reported comparative results from primary CTC (with selective recommendation for therapeutic colonoscopy) and primary OC screening arms among 3,120 and 3,163 mostly asymptomatic adults, respectively.[172] Although this study did not randomize participants to CTC versus OC, apart from a slightly higher proportion of individuals with a family history in the OC group, the 2 groups were similar. Similar rates of advanced neoplasia were found in each group, with 3.2% in the CTC group and 3.4% in the OC group.[172]

CTC—Benefits, Limitations, and Harms. CTC provides a time-efficient procedure with good accuracy and minimal invasiveness. No sedation or recovery time is required, nor is a chaperone needed to provide transportation after the procedure. Time permitting, patients can return to work on the same day. However, some limitations to CTC exist, ranging from access issues to potential harms from the examination. Because CTC is relatively early in its utilization, there are fewer data relative to other CRC screening tests for evaluating benefits, limitations, and harms. Thus, continued development of best practice standards is a high priority, as is monitoring the performance of CTC as access and utilization increases. At this time, reimbursement for screening CTC is very limited, although 47 states now offer Medicare reimbursement for diagnostic CTC where the clinical indication is limited to incomplete OC.[173] However, because reimbursement for screening still is uncommon, the current professional capacity to deliver CTC also is limited, although capacity is expected to increase when third-party payers begin providing reimbursement for screening.

CTC requires the same full cathartic bowel preparation and restricted diet as colonoscopy, which may decrease patient adherence. As an "imaging-only," nontherapeutic evaluation of the colon, patients with polyps of significant size will require therapeutic colonoscopy for subsequent polypectomy. Thus, it is possible to offer same-day polypectomy to patients for whom colonoscopy is recommended without the need for additional bowel preparation, although this convenience for patients requires coordination between radiology and gastroenterology departments.[174] Where such coordination does not exist, patients will need to undergo an additional

bowel preparation. While older oral tagging protocols would have precluded same-day colonoscopy, revised, more efficient tagging protocols have successfully allowed therapeutic colonoscopy on the same day.

CTC is similar to endoscopy and DCBE with respect to the quality of interpretation being highly operator dependent, and thus initiatives towards training and certification are important. Detection of flat lesions has been variable, ranging from sensitivities of 13% to 65% in early CTC studies[175] to 80% when using multidetector CT and combined 3D-2D polyp detection.[176] However, debate continues over the prevalence and significance of flat colorectal lesions.[177–179]

The accuracy of CTC is influenced by lesion size, and the sensitivity and specificity of CTC improves with polyp size. The accuracy of CTC in measuring polyp size is of particular importance since accurate size estimation is critical for appropriate patient management and for minimizing the false-positive rate. While earlier studies using rudimentary software applied to wide-slice thicknesses and 2D images showed poor concordance with prefixation polyp size,[180] modern CT technology producing 3D images results in more accurate size estimates.[181–183] The ability to ensure consistent polyp size measurements during examinations is a high priority for quality-assurance initiatives since it will influence referrals for polypectomy. Pickhardt et al showed that specificity (when polyps were matched for size) was 97.4% for lesions ≥1 cm but declines to 84.5% for all lesions to all lesions ≥6mm.[167] The incremental increase in the false-positive rate associated with polyps between 6 to 8 mm could add significantly to the cost of screening, and thus it will be important to monitor sensitivity and specificity in the clinical setting and identify strategies to improve specificity without diminishing sensitivity.

There is controversy over the long-term potential harms associated with radiation dose effects from CT examinations. One aspect of this controversy relates to risk-estimation models, and the other pertains to the long-term risk of cancer from single and repeated medical imaging exposures.[184, 185] While current estimates of the potential cancer risk related to low-dose radiation exposures during medical procedures derive from linear nonthreshold models based on long-term outcomes in survivors of acute radiation doses from atomic weapons, there is disagreement over whether this model truly is applicable to periodic exposures from medical imaging.[186] In a recent position statement issued by the Health Physics Society, the health effects of low-dose radiation exposure (defined as below 50 to 100 mSv—a threshold many times higher than typical CTC levels) were considered to be "either too small to be observed or are nonexistent."[187] Nevertheless, although this risk may be theoretical, there is a growing concern that more individuals are receiving multiple diagnostic evaluations with ionizing radiation over a lifetime and that for some individuals the doses over a lifetime can reach levels that are sufficiently high to be of concern. It is important to put these issues into context with respect to screening with CTC.

Using the linear, no-threshold radiation-risk estimate, a CTC examination in a 50-year-old individual with an estimated organ dose to the colon of 7 to 13 mSv (65 mAs) is estimated to add an additional 0.044% to the lifetime risk of colon cancer.[188] Because organ radiosensitivity declines with increasing age, this organ dose is halved for the same examination taking place at age 70 years. In this same evaluation, the additional lifetime risk of cancer in any site associated with a single CTC examination at age 50 years was 0.14%, although the authors stated with optimized techniques this risk could be reduced by a factor of 5- to10-fold. More efficient dose protocols using 50 mAs on 4DCT, similar to the ACR-defined protocols, have demonstrated decreased estimated organ dose ranges of 5 to 8 mSv.[189] While acknowledging there is uncertainty about potential harms from single or multiple CTC screening examinations, current ACR quality metrics for CTC define low-dose parameters as a best practice for minimizing risk to patients.[190]

Since CTC is a minimally invasive test, the risk for colonic perforation during screening is extremely low. In the collective experience of the International Working Group on Virtual Colonoscopy, there were no cases of perforation in over 11,000 screening CTC examinations, and out of nearly 22,000 total CTC examinations (screening and diagnostic), there was only one

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symptomatic perforation, corresponding to a symptomatic perforation rate of 0.005%.[191] Some studies of symptomatic patients, however, have reported higher perforation rates, ranging from 0.03% (1 in 3,400 patients) to 0.06% (1 in 1,700 patients).[192,193] Colonic distention with low-pressure carbon dioxide delivery may be safer than insufflation of room air.[191] Rates of perforation are part of the quality metrics being collected by the ACR.

Because CTC produces an image not only of the colon but also the upper and lower abdomen, there is a chance that incidental extracolonic findings will be observed. Although the overall rates of extracolonic findings have been reported to range from 15% to 69%, the incidence of clinically significant extracolonic findings at CTC has ranged from 4.5% to 11% in various patient cohorts.[194–197] In an asymptomatic screening population, the incidence of unsuspected but potentially important extracolonic findings is approximately 4.5%, but findings of minimal or moderate potential clinical significance, such as cholelithiasis (6%) and nephrolithiasis (8%), are more common.[197] While there are potential benefits from serendipitous findings, there also are associated risks and costs that need to be considered when these findings are false positives. These include further radiologic imaging and, thus, added organ dose, potential for adverse outcomes associated with tissue sampling for abnormalities that are not resolved with additional imaging, as well as the direct and indirect costs to the patient. The implementation of structured reporting of extracolonic findings and monitoring trends in subsequent diagnostic workups and adherence with quality metrics are being evaluated through the National Radiology Data Registry (NRDR), the ACR's national data warehouse.

Quality Assurance. Similar to the call to action for measuring quality of colonoscopy,[198] the implementation of CTC will require quality metrics to be defined and implemented in clinical practice. Quality of CTC examinations will depend on (1) proper bowel preparation; (2) adequate insufflation of the colon and appropriate use of CTC technique parameters at image acquisition; (3) adequate training of the interpreting physician in the use of 2D- and 3D-image display techniques; and (4) documentation of clinically significant colonic and extracolonic lesions to referring physicians. In 2005, the *ACR Practice Guidelines for the Performance of Computed Tomography (CT) Colonography in Adults* was published, encompassing the techniques, quality control, clinical uses, training, and communication of results for CTC.[190] An update of these guidelines is planned following publication of the results of the ACRIN CTC screening trial. In 2006, the ACR Colon Cancer Committee outlined practice-based quality metrics for CTC, encompassing process measures of CTC technique and image quality; patient preparation; and outcomes measures such as rates of true positives, colonic perforation, and incidence of extracolonic findings. These quality metrics are to begin a pilot phase in late 2007, with data entry in the NRDR database. The ACR has begun construction of an interactive, hands-on training facility for CTC and will begin training courses in early 2008. A process for individual certification and proficiency is being evaluated.

CTC—Other Issues. Standardization of the evolving technology and consensus related to the reporting of findings will be essential for effective implementation of CTC screening. A consensus statement of a standardized reporting structure for CTC findings was recently published, modeled after the Breast Imaging Reporting and Data System's (BI-RADS) reporting of mammography.[199] This reporting structure, termed the "CT Colonography Reporting and Data System (C-RADS)," describes how to report lesion size, morphology, and location, with a summary category score per patient.

The management of CTC findings is an important part of a CTC screening program. At this time, there is consensus that all patients with one or more polyps ≥10 mm or 3 or more polyps ≥6 mm should be referred for colonoscopy.[200] The management of patients with fewer polyps (<3) in which the largest polyp is 6 to 9 mm remains controversial. Such polyps are routinely removed if found at OC because of the opportunity and the risk, albeit low, of advanced neoplasia. However, in studies that have been limited to screening cohorts, among individuals whose largest polyp is 6 to 9 mm in size, the prevalence of advanced features tends to be low (3.4% to 6.6%).[201,202] At this time, there is ongoing research

using CTC surveillance to evaluate the natural history of polyps in this size range. Based on expert consensus and until further evidence is available to provide additional guidance, a reasonable approach at this time for patients with 6 to 9 mm polyps identified on CTC is to recommend therapeutic colonoscopy. Patients who decline referral to colonoscopy or who are not good candidates for colonoscopy should be offered surveillance with CTC.

Optimal management of patients whose largest polyp is <6 mm detected on CTC is uncertain. Experts from the American Gastroenterological Association, the American College of Gastroenterology, and the ACR have reported a range of policies on how to handle these lesions.[190,203,204] There is general agreement that the risk of advanced features in patients whose largest polyp is ≤5 mm is very low. In a recent study that is able to provide this estimate in a screening cohort, the prevalence of advanced neoplasia in patients whose largest polyp was ≤5 mm was 1.7% (D.A.L, personal communication, December 14, 2007).[202] At this time, there is a pressing need for multidisciplinary consensus on the reporting and clinical management of patients whose largest polyp is <6 mm.

CTC—Conclusions and Recommendations. In terms of detection of colon cancer and advanced neoplasia, which is the primary goal of screening for CRC and adenomatous polyps, recent data suggest CTC is comparable to OC for the detection of cancer and polyps of significant size when state-of-the-art techniques are applied. In previous assessments of the performance of CTC, the ACS concluded that data were insufficient to recommend screening with CTC for average-risk individuals.[19] Based on the accumulation of evidence since that time, the expert panel concludes that there are sufficient data to include CTC as an acceptable option for CRC screening.

Screening of average-risk adults with CTC should commence at age 50 years. The interval for repeat exams after a negative CTC has not been studied, and is uncertain. However, if current studies confirm the previously reported high sensitivity for detection of cancer and of polyps ≥6 mm, it would be reasonable to repeat exams every 5 years if the initial CTC is negative for significant polyps until further studies are completed and are able to provide additional guidance. Until there is more research on the safety of observation, colonoscopy should be offered to patients whose largest polyp is 6 mm or greater. CTC surveillance could be offered to those patients who would benefit from screening but either decline colonoscopy or who are not good candidates for colonoscopy for one or more reasons. However, if colonoscopy is contraindicated because the patient is not likely to benefit from screening due to life-limiting comorbidity, then neither CTC nor any other CRC screening test would be appropriate.

CONCLUSION

There is compelling evidence to support screening average-risk individuals over age 50 years to detect and prevent CRC. Screening of average-risk individuals can reduce CRC mortality by detecting cancer at an early, curable stage and by detecting and removing clinically significant adenomas. No CRC screening test is perfect, either for cancer detection or adenoma detection. Each test has unique advantages, each has been shown to be cost-effective,[205–208] and each has associated limitations and risks. Patient preferences and availability of resources play an important role in the selection of screening tests. In this update of the guidelines for CRC screening, we have placed an emphasis on the value of preventing CRC, sought to address the importance of test sensitivity in the presence of low rates of programmatic screening, and attempted to provide improved guidance about test characteristics and quality issues to referring clinicians. Ideally, screening should be supported in a programmatic fashion that begins with risk stratification and the results from an initial test and continues through proper follow up based on findings. The effectiveness of any single test or combination of tests depends on high rates of programmatic adherence and quality.

Based on differing incidence rates and observations of different patterns of polyp and cancer distribution in certain subsets of patients (ie, the elderly, women, and ethnic minorities, etc.), some experts have suggested that these groups may require different screening recommendations.[209,210] The expert panel reviewed and discussed the evidence and rationale for and against including different screening recommendations in this update for various demographic subgroups that have been shown to be

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TABLE **3** Guidelines for Screening and Surveillance for the Early Detection of Colorectal Adenomas and Cancer in Individuals at Increased Risk or at High Risk

Risk Category	Age to Begin	Recommendation	Comment
Increased Risk—Patients with History of Polyps at Prior Colonoscopy			
Patients with small rectal hyperplastic polyps[26]	—	Colonoscopy or other screening options at intervals recommended for average-risk individuals	An exception is patients with a hyperplastic polyposis syndrome. They are at increased risk for adenomas and colorectal cancer and need to be identified for more intensive follow up.
Patients with 1 or 2 small tubular adenomas with low-grade dysplasia[26]	5 to 10 years after the initial polypectomy	Colonoscopy	The precise timing within this interval should be based on other clinical factors (such as prior colonoscopy findings, family history, and the preferences of the patient and judgment of the physician).
Patients with 3 to 10 adenomas or 1 adenoma >1 cm or any adenoma with villous features or high-grade dysplasia[26]	3 years after the initial polypectomy	Colonoscopy	Adenomas must have been completely removed. If the follow-up colonoscopy is normal or shows only 1 or 2 small, tubular adenomas with low-grade dysplasia, then the interval for the subsequent examination should be 5 years.
Patients with >10 adenomas on a single examination[26]	<3 years after the initial polypectomy	Colonoscopy	Consider the possibility of an underlying familial syndrome.
Patients with sessile adenomas that are removed piecemeal[26]	2 to 6 months to verify complete removal	Colonoscopy	Once complete removal has been established, subsequent surveillance needs to be individualized based on the endoscopist's judgment. Completeness of removal should be based on both endoscopic and pathologic assessments.
Increased Risk—Patients with Colorectal Cancer			
Patients with colon and rectal cancer should undergo high-quality perioperative clearing[25]	3 to 6 months after cancer resection, if no unresectable metastases are found during surgery; alternatively, colonoscopy can be performed intraoperatively	Colonoscopy	In the case of nonobstructing tumors, this can be done by preoperative colonoscopy. In the case of obstructing colon cancers, CTC with intravenous contrast or DCBE can be used to detect neoplasms in the proximal colon.
Patients undergoing curative resection for colon or rectal cancer[2]	1 year after the resection (or 1 year following the performance of the colonoscopy that was performed to clear the colon of synchronous disease)	Colonoscopy	This colonoscopy at 1 year is in addition to the perioperative colonoscopy for synchronous tumors. If the examination performed at 1 year is normal, then the interval before the next subsequent examination should be 3 years. If that colonoscopy is normal, then the interval before the next subsequent examination should be 5 years. Following the examination at 1 year, the intervals before subsequent examinations may be shortened if there is evidence of HNPCC or if adenoma findings warrant earlier colonoscopy. Periodic examination of the rectum for the purpose of identifying local recurrence, usually performed at 3- to 6-month intervals for the first 2 or 3 years, may be considered after low-anterior resection of rectal cancer.
Increased Risk—Patients with a Family History			
Either colorectal cancer or adenomatous polyps in a first-degree relative before age 60 years or in 2 or more first-degree relatives at any age[24]	Age 40 years or 10 years before the youngest case in the immediate family	Colonoscopy	Every 5 years
Either colorectal cancer or adenomatous polyps in a first-degree relative ≥age 60 years or in 2 second-degree relatives with colorectal cancer[24]	Age 40 years	Screening options at intervals recommended for average-risk individuals	Screening should begin at an earlier age, but individuals may choose to be screened with any recommended form of testing.

—Continued

TABLE **3** (continued)

Risk Category	Age to Begin	Recommendation	Comment
High Risk			
Genetic diagnosis of FAP or suspected FAP without genetic testing evidence[24]	Aged 10 to 12 years	Annual FSIG to determine if the individual is expressing the genetic abnormality and counseling to consider genetic testing.	If the genetic test is positive, colectomy should be considered.
Genetic or clinical diagnosis of HNPCC or individuals at increased risk of HNPCC[24]	Aged 20 to 25 years or 10 years before the youngest case in the immediate family	Colonoscopy every 1 to 2 years and counseling to consider genetic testing	Genetic testing for HNPCC should be offered to first-degree relatives of persons with a known inherited MMR gene mutation. It should also be offered when the family mutation is not already known, but 1 of the first 3 of the modified Bethesda Criteria is present.
Inflammatory bowel disease,[24] chronic ulcerative colitis, and Crohn's colitis	Cancer risk begins to be significant 8 years after the onset of pancolitis or 12 to 15 years after the onset of left-sided colitis	Colonoscopy with biopsies for dysplasia	Every 1 to 2 years; these patients are best referred to a center with experience in the surveillance and management of inflammatory bowel disease

Abbreviations: FSIG, flexible sigmoidoscopy; DCBE, double-contrast barium enema; CTC, computed tomographic colonography; FAP, familial adenomatous polyposis; HNPCC, hereditary nonpolyposis colon cancer; MMR, mismatch repair.

at somewhat higher or lower than average risk for disease or proximal lesions. After some consideration, this issue was postponed for further consideration at a later time for a number of reasons, although principally because (1) there are no current data to indicate that CRC incidence and mortality in these groups would be positively impacted by tailored screening recommendations; and (2) screening rates among all groups remain low under existing guidelines and providing different (and, in some cases, more limited) screening options has the potential to increase confusion, complexity, and workload, and thus might add additional barriers to screening that would affect all groups. This is an area of research that the collaborating organizations will continue to monitor closely.

In this update of the CRC screening guidelines, we have focused on screening in average-risk adults and have not reviewed recent literature on CRC screening or surveillance for individuals at increased and high risk. Individuals at increased risk due to a history of adenomatous polyps; a personal history of curative-intent resection of CRC; a family history of either CRC or colorectal adenomas diagnosed in a first-degree relative before age 60 years; or high risk due to a history of inflammatory bowel disease of significant duration or the presence of one of 2 hereditary syndromes should continue to follow recommendations issued previously by the ACS or USMSTF.[18,24] These recommendations are summarized in Table 3.

There appears to be a clear need for institutionally based quality-assurance programs to improve the quality of CRC screening. This guideline update emphasizes issues for quality assurance across colorectal screening modalities, spanning training requirements, optimal techniques to complete examination, screening intervals, and appropriate recommendations for follow up. In contrast, cost-effectiveness is not specifically discussed in this document, based on the numerous complexities of adequately addressing this topic, including understanding real costs in different environments, differences in test performance and interpretation, and wide variability of screening intervals in different settings. It is hoped that compliance with improvements in quality assurance will both improve quality and promote cost-effectiveness.

Clearly, better definition of the target lesion of clinical importance is needed across modalities. As new technologies evolve that detect but do not remove polyps, multidisciplinary consensus is needed to best manage a patient programmatically for follow-up polypectomy versus surveillance intervals. Although there are some ongoing studies of the natural history of small

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polyps, evidence-based data will probably take 10 to 20 years to meaningfully translate into clinical-practice recommendations. In this interim, the current recommendations try to address these issues with expert consensus based on existing data. Multidisciplinary groups, such as the National Colorectal Cancer Roundtable, may be able to serve as an effective forum for the development of a consensus across specialties about the reporting and follow up of small polyps.

In conclusion, it is our hope that these new recommendations will facilitate increased rates of CRC screening and that referring clinicians find these new guidelines ease some of the challenges they have experienced in promoting CRC screening to their patients.

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Erratum

In the article "Screening and Surveillance for the Early Detection of Colorectal Cancer and Adenomatous Polyps, 2008: A Joint Guideline from the American Cancer Society, the US Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology" (*CA Cancer J Clin* 2008, published online March 5, 2008), the names of 3 authors, John Bond, MD (Chief, Gastroenterology Section, Minneapolis Veterans Affairs Medical Center, Minneapolis, MN), C. Daniel Johnson, MD (Chairman and Professor of Radiology, Radiology Department, Mayo Clinic, Scottsdale, AZ), and David A. Johnson, MD (Professor of Medicine, Chief of Gastroenterology, Eastern Virginia Medical School, Norfolk, VA), were inadvertently omitted. The author list should correctly read: Bernard Levin, MD; David A. Lieberman, MD; Beth McFarland, MD; Robert A. Smith, PhD; Durado Brooks, MD, MPH; Kimberly S. Andrews; John Bond, MD; Chiranjeev Dash, MD, MPH; Francis M. Giardiello, MD; Seth Glick, MD; C. Daniel Johnson, MD; David A. Johnson, MD; Theodore R. Levin, MD; Perry J. Pickhardt, MD; Douglas K. Rex, MD; Alan Thorson, MD; Sidney J. Winawer, MD; for the American Cancer Society Colorectal Cancer Advisory Group, the US Multi-Society Task Force, and the American College of Radiology Colon Cancer Committee.

In addition, the American Gastroenterological Association (AGA) Institute was incorrectly identified in the joint publication and copyright statements. The statements should read:

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The authors regret the errors.

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Guidelines for Colonoscopy Surveillance after Polypectomy: A Consensus Update by the US Multi-Society Task Force on Colorectal Cancer and the American Cancer Society*,†

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ABSTRACT Adenomatous polyps are the most common neoplastic findings uncovered in people who undergo colorectal screening or have a diagnostic workup for symptoms. It was common practice in the 1970s for these patients to have annual follow-up surveillance examinations to detect additional new adenomas as well as missed synchronous adenomas. As a result of the National Polyp Study report in 1993, which demonstrated clearly in a randomized design that the first postpolypectomy examination could be deferred for 3 years, guidelines published by a gastrointestinal consortium in 1997 recommended that the first follow-up surveillance be 3 years after polypectomy for most patients. In 2003, these guidelines were updated, colonoscopy was recommended as the only follow-up examination, and stratification at baseline into lower and higher risk for subsequent adenomas was suggested. The 1997 and 2003 guidelines dealt with both screening and surveillance. However, it has become increasingly clear that postpolypectomy surveillance is now a large part of endoscopic practice, draining resources from screening and diagnosis. In addition, surveys have demonstrated that a large proportion of endoscopists are conducting surveillance examinations at shorter intervals than recommended in the guidelines. In the present paper, a careful analytic approach was designed addressing all evidence available in the literature to delineate predictors of advanced pathology, both cancer and advanced adenomas, so that patients can be more definitely stratified at their baseline colonoscopy into those at lower or increased risk for a subsequent advanced neoplasia. People at increased risk have either three or more adenomas, or high-grade dysplasia, or villous features, or an adenoma ≥1 cm in size. It is recommended that they have a 3-year follow-up colonoscopy. People at lower risk who have one or two small (<1 cm)

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(continued next page)

Guidelines for Colonoscopy Surveillance after Polypectomy

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tubular adenomas with no high-grade dysplasia can have a follow up in 5 to 10 years, whereas people with hyperplastic polyps only should have a 10-year follow up as average-risk people. Recent papers have reported a significant number of missed cancers by colonoscopy. However, high-quality baseline colonoscopy with excellent patient preparation and adequate withdrawal time should minimize this and reduce clinicians' concerns. These guidelines were developed jointly by the US Multi-Society Task Force on Colorectal Cancer and the American Cancer Society to provide a broader consensus and thereby increase utilization of the recommendations by endoscopists. Adoption of these guidelines nationally can have a dramatic impact on shifting available resources from intensive surveillance to screening. It has been shown that the first screening colonoscopy and polypectomy produces the greatest effects on reducing the incidence of colorectal cancer in patients with adenomatous polyps. (*CA Cancer J Clin 2006;56:143–159.*) © *American Cancer Society, Inc., 2006.*

INTRODUCTION

Adenomatous polyps are the most frequent neoplasm found during colorectal screening.[1–4] Removal of these lesions has been shown to reduce the risk of future colorectal cancer and advanced adenomas.[5–12] To further minimize the risk of colorectal cancer, patients with adenomas are usually placed into a surveillance program of periodic colonoscopy to remove missed synchronous and new metachronous adenomas and cancers.[13–16] A large number of patients with adenomas are now being uncovered as a result of the increased utilization of colorectal cancer screening, particularly the dramatic increase in screening colonoscopy, which places a huge burden on medical resources applied to surveillance.[17–19] Therefore, there is a need for increased efficiency of surveillance colonoscopy practices to decrease the cost, risk, and overutilization of resources for unnecessary examinations.

Therefore, the US Multi-Society Task Force on Colorectal Cancer and the American Cancer Society (ACS) have decided to issue updated joint guidelines on postpolypectomy surveillance. These guidelines differ from the earlier guidelines in several specific ways (Table 1)[13–16]: we offer a consensus statement that strengthens the guidelines; we specifically examined predictors of advanced adenomas and incorporated them into the guidelines; and we emphasize the quality of baseline colonoscopy and its impact on detection of postpolypectomy colorectal cancer.[5,20,21] We reviewed recent evidence, particularly as it pertains to stratifying patients for future risk of advanced adenomas.

Risk stratification could markedly reduce the intensity of follow up in a substantial proportion of patients, so that colonoscopy resources could be shifted from surveillance to screening and diagnosis. Risk stratification could also reduce the small, but finite, screening colonoscopy complication rate.[22] This set of guidelines is the latest in a series begun in 1997, updated in 2003, and built on the concept of change consistent with new evidence.[13–16] It incorporates the American College of Gastroenterology polyp guidelines from 2000.[23] Before the above guidelines, physicians had minimal guidance in managing postpolypectomy patients. Our goal is to provide a continuing basis for recommendations to guide postpolypectomy follow up.

These guidelines (Tables 2 and 3) have been endorsed by the Colorectal Cancer Advisory Committee of the ACS and by the governing boards of the American College of Gastroenterology, the American Gastroenterological Association, and the American Society for Gastrointestinal Endoscopy.

METHODOLOGY AND LITERATURE REVIEW

We performed a Medline search of the postpolypectomy literature under the subject headings *colonoscopy* and *adenoma*, *polypectomy*

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TABLE **1** Differences from Prior Postpolypectomy Guidelines

1. The overall goal of these guidelines is to identify predictors of subsequent advanced adenomas and cancers to stratify patients into lower- and higher-risk groups.
2. These guidelines focus on the above risk stratification to encourage a shift from intense surveillance to surveillance based on risk. This would free up endoscopic resources for screening, diagnosis, and appropriate surveillance.
3. High-quality baseline colonoscopy is emphasized as critical for effectively reducing colon cancer risk.
4. Completeness of polypectomy at baseline is emphasized, particularly in the setting of piecemeal removal of large sessile polyps.
5. Follow-up surveillance of hyperplastic polyps is discouraged, except in the case of hyperplastic polyposis.
6. The importance of increasing awareness of hyperplastic polyposis is discussed.
7. The use of fecal occult blood testing during surveillance is discouraged at present but requires further study.
8. Follow-up intervals after removal of one or two small (<1 cm) adenomas have been lengthened (5 to 10 years or average risk screening options), and within this range, left to the clinician's judgment and the patient's preference.
9. Evolving technologies such as chromoendoscopy, magnification endoscopy, and CT colonography (virtual colonoscopy) are not yet established as surveillance modalities.

TABLE **2** Surveillance Recommendations

1. **Patients with small rectal hyperplastic polyps** should be considered to have normal colonoscopies, and therefore the interval before the subsequent colonoscopy should be 10 years. An exception is patients with a hyperplastic polyposis syndrome. They are at increased risk for adenomas and colorectal cancer and need to be identified for more intensive follow up.
2. **Patients with only one or two small (<1 cm) tubular adenomas with only low-grade dysplasia** should have their next follow-up colonoscopy in 5 to 10 years. The precise timing within this interval should be based on other clinical factors (such as prior colonoscopy findings, family history, and the preferences of the patient and judgment of the physician).
3. **Patients with 3 to 10 adenomas, or any adenoma ≥ 1 cm, or any adenoma with villous features, or high-grade dysplasia** should have their next follow-up colonoscopy in 3 years providing that piecemeal removal has not been done and the adenoma(s) are completely removed. If the follow-up colonoscopy is normal or shows only one or two small tubular adenomas with low-grade dysplasia, then the interval for the subsequent examination should be 5 years.
4. **Patients who have more than 10 adenomas at one examination** should be examined at a shorter (<3 years) interval established by clinical judgment, and the clinician should consider the possibility of an underlying familial syndrome.
5. **Patients with sessile adenomas that are removed piecemeal** should be considered for follow up at short intervals (2 to 6 months) to verify complete removal. Once complete removal has been established, subsequent surveillance needs to be individualized based on the endoscopist's judgment. Completeness of removal should be based on both endoscopic and pathologic assessments.
6. **More intensive surveillance is indicated when the family history may indicate hereditary nonpolyposis colorectal cancer**.

TABLE **3** Additional Surveillance Considerations

1. The present recommendations assume that colonoscopy is complete to the cecum and that bowel preparation is adequate. A repeat examination should be done if the bowel preparation is not adequate before planning a long-term surveillance program.
2. There is clear evidence that the quality of examinations is highly variable. A continuous quality improvement process is critical to the effective application of colonoscopy in colorectal cancer prevention.
3. A repeat examination is warranted if there is a concern that the polyp is incompletely removed, particularly if it shows high-grade dysplasia.
4. Endoscopists should make clear recommendations to primary care physicians about when the next colonoscopy is indicated.
5. Given the evolving nature of guidelines, it is important that physicians and patients should remain in contact so that surveillance recommendations reflect changes in guidelines.
6. Pending further investigation, performance of fecal occult blood test is discouraged in patients undergoing colonoscopic surveillance.
7. Discontinuation of surveillance colonoscopy should be considered in persons with serious comorbidities with less than 10 years of life expectancy, according to the clinician's judgment.
8. Surveillance guidelines are intended for asymptomatic people. New symptoms may need diagnostic workup.
9. The application of evolving technologies such as chromoendoscopy, magnification endoscopy, narrow-band imaging, and computed tomography colonography are not established for postpolypectomy surveillance at this time.

surveillance, and *adenoma surveillance*, limited to English language from 1990 to 2005. This search identified 35 articles based on inclusion of data pertaining to baseline colonoscopy characteristics, advanced adenoma detection during follow-up surveillance, and advanced adenoma characteristics. Subsequently, we identified 12 additional articles from references of reviewed articles. Of these 47 articles, we considered 13 to be relevant studies according to the following criteria: 1) colonoscopy studies specifically addressing the relationship between baseline examination findings and detection of advanced adenoma or of any adenoma during follow-up colonoscopy; or 2) sigmoidoscopy studies, with large cohorts and follow up

greater than 10 years, specifically addressing the association between baseline examination findings and detection of advanced adenomas during follow up. After the initial review of published data, we added one relevant abstract and a newly published article to the review. These were studies that were identified by members of the guideline committee and for which the data were available to the committee. We excluded studies that included patients with inflammatory bowel disease, prior history of colorectal cancer, and familial syndromes. Our final review was based on 15 studies that met the inclusion criteria.[5,7,12,20,21,24–35] The most recent publication for the outcome of interest (adenomas and advanced neoplasia) was used for studies with more than one publication. We gave separate listings to the St. Mark's study by Atkin[7] for the outcomes for colon cancer and for rectal cancer. Two studies reported only on risk factors for adenomas rather than for advanced adenomas at surveillance.[32,34]

The literature review was conducted by two independent authors (SJW and JSS). A third author (AGZ) created the evidence table, which was circulated among members of the US Multi-Society Task Force on Colorectal Cancer and the ACS's Colorectal Cancer Advisory Committee. Recommendations in this report were based on the review of the evidence and the discussions at the combined meeting.

The evidence table (accessible at http://caonline.amcancersoc.org/content/vol56/issue3/) was organized to include the elements of study design. Ideally, the best study design would fulfill the following criteria: (1) be a randomized controlled trial or an observational cohort study of patients with adenoma(s) at baseline that were cleared by colonoscopy, after excluding people at high risk (such as familial syndromes); (2) consider all the candidate risk factors; (3) have sufficient follow-up time for adenomas to develop, with few dropouts; (4) have planned colonoscopic assessment for recurrence in all patients in the cohort; (5) have enough outcome events for reasonable statistical precision and sufficient statistical power to detect associations between baseline characteristics and adenoma outcomes; and (6) present the analyses that include adjustment for multiple risk factors and consider what the independent effects are.

The evidence table (accessible at http://caonline.amcancersoc.org/content/vol56/issue3/) includes classification of the type of design (randomized controlled trials [RCTs] or observational cohort studies), the number at risk, the follow-up intervals recommended, and the time followed. We also list the variables considered as risk factors and the effect of these factors on incidence of subsequent adenomas or on advanced neoplasia. The multivariate estimate of the relative risk is presented whenever available. The definition of an advanced neoplasia is given for each study and varies considerably by study. Summary comments on each study are also included.

Review of the evidence was confounded by variations in definitions, design of studies, timing and multiplicity of surveillance intervals, and quality of baseline colonoscopy (evidence tables accessible at http://caonline.amcancersoc.org/content/vol56/issue3/). Due to these variations, the review of the literature cited was descriptive rather than a single summary value of risk (ie, meta-analysis) for all studies. The literature cited is grouped by type of study design: (1) RCTs, where the surveillance interval is set and maintained as much as possible though eligibility requirements may vary; or (2) observational cohort studies, which are primarily registry studies with more passive recruitment for surveillance. The RCTs provide stronger evidence for the timing of follow-up examinations because those who received surveillance colonoscopy were not a special subset of all enrolled. As noted above, relative risks (RR) or odds ratios (OR) from multivariate analysis were presented in the evidence table whenever available. For two studies,[7,21] the measure of risk was the standardized incidence ratio (SIR) with adjustment for age and sex rather than a relative risk. In one study,[12] the hazard ratio (HR) is given as the measure of the effect. A descriptive graphical presentation was given with point estimates and confidence intervals for the relative risk for adenomas and advanced neoplasia by baseline adenoma characteristics of multiplicity, size, histology, high-grade

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dysplasia, and location. These descriptive plots (Figure 1) of the measure of the effect for various risk factors provide a summary of the number of studies reporting a measure of effect for a given risk factor and the consistency and magnitude of this factor on adenoma and advanced neoplasia recurrence. The review of evidence assessed the risk factors for adenomas as well as for advanced adenomas, but the discussion concentrated on the factors affecting advanced adenomas. The definition of advanced adenoma differs from study to study.[36] The most encompassing definition included any adenoma ≥1.0 cm, any villous component (ie, nontubular), or high-grade dysplasia, or invasive cancer.

Given the concern in detecting colorectal cancers at surveillance, the number of colorectal cancers detected by time under surveillance is cited whenever these data are included in the published study. Special characteristics of the study population and selection for the cohort were also noted in the evidence tables (accessible at http://caonline.amcancersoc.org/content/vol56/issue3/).

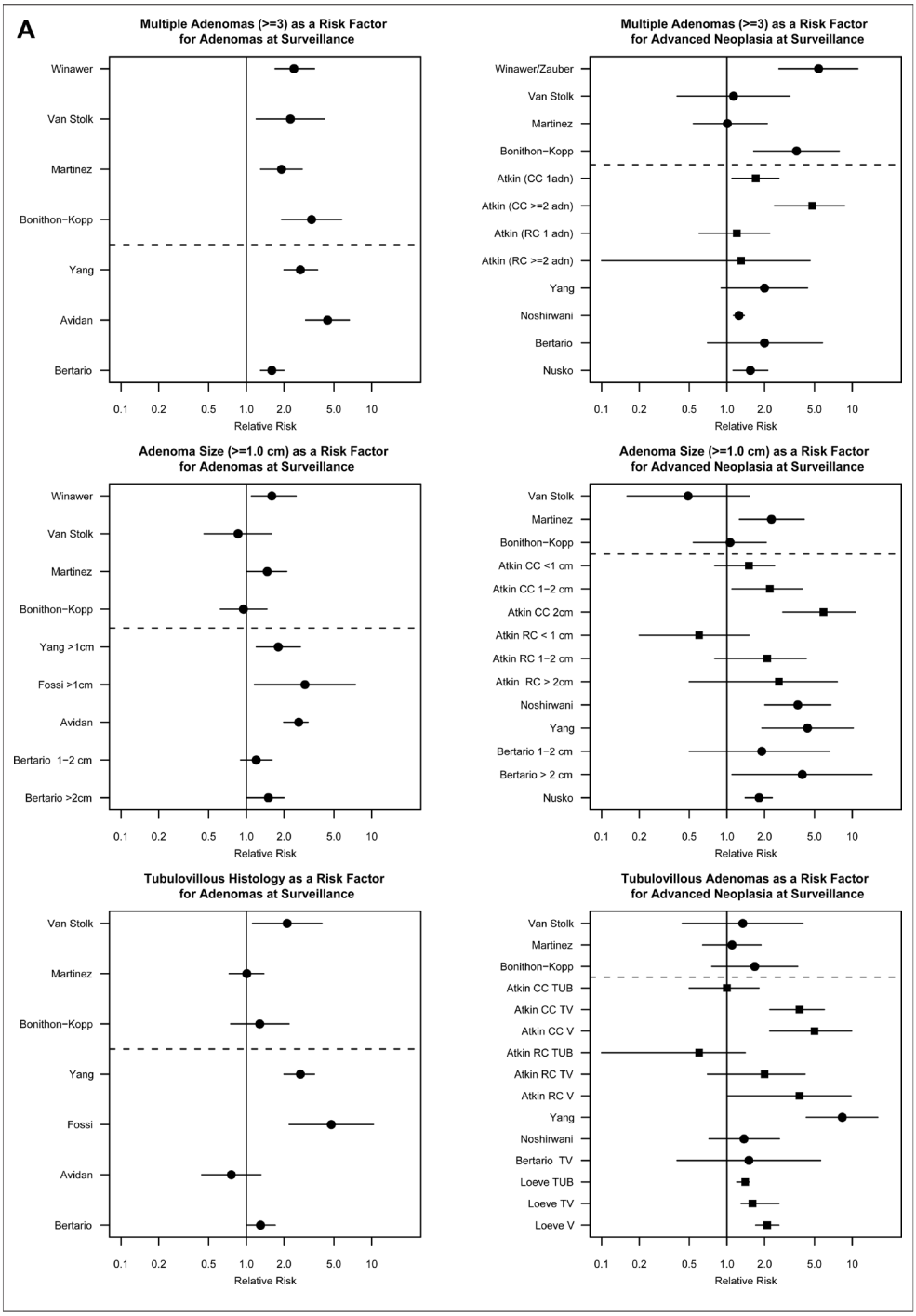
RESULTS OF THE LITERATURE REVIEW AND RATIONALE FOR THE GUIDELINES

Certain characteristics of colorectal adenomas at baseline colonoscopy are associated with the rate of adenoma detection and the histologic severity of subsequent adenomas. These data can be used as the basis for decisions about safe and effective postpolypectomy surveillance intervals by stratifying patients into lower- and higher-risk groups for future advanced adenomas. The available body of evidence is the basis for these recommendations.

Quality of Baseline Colonoscopy

Baseline adenoma characteristics play a major role in determining appropriate postpolypectomy surveillance intervals. Characteristics of the baseline colonoscopy are also an important predictor for subsequent neoplasia. The baseline colonoscopy needs to be of high quality for the baseline adenoma characteristics to be used for planning surveillance intervals. As defined by the US Multi-Society Task Force, a high quality colonoscopy reaches the cecum, has little fecal residue, and has a minimum time of withdrawal from the cecum of 6 to 10 minutes.[37] Baseline colonoscopy without a good clearing of the colon places the patient at increased risk for subsequent neoplastic findings.[38] Adenomas, advanced adenomas, and cancers are missed by colonoscopy.[39–42] Sensitivity could be increased by continuing quality improvement programs for the performance of colonoscopy.[37] Trials designed specifically to evaluate surveillance, in which colonoscopy is performed by experienced endoscopists, such as the National Polyp Study (NPS), have demonstrated that a low incidence of cancer can be achieved in postpolypectomy patients.[5,25,43] The NPS required meticulous clearing at the initial baseline with repeat colonoscopy if this was not achieved with high confidence.

On the other hand, studies designed for other purposes, such as the pooled chemoprevention studies reported by Robertson et al,[20] and community studies clearly show that higher miss rates commonly occur.[39] Incomplete removal of large sessile polyps, particularly by piecemeal polypectomy, could contribute to a higher subsequent incidence of a colon cancer as in the chemoprevention trials.[20,44] Atkin[7] also demonstrated that inadequate removal of sessile rectosigmoid adenomas at baseline was associated with a marked increase in risk for rectal cancer. The NPS exclusion of patients with sessile adenomas larger than 3.0 cm and provision for individualized follow up for these patients could be another factor that contributed to the low incidence of cancer at follow up in this study.[5] Loeve assessed colorectal cancer incidence after adenoma detection in Holland based on 78,473 patients and found that colorectal cancer incidence was not greatly reduced until 5 to 6 years after the initial diagnosis and attributed the lack of earlier effect to inadequate removal of adenomas when initially diagnosed.[21] It is therefore important to consider early and late appearing cancers separately in postpolypectomy trials to separate true incidence reduction from missed cancers. This point is illustrated in the chemoprevention trials, in which a


A
Multiple Adenomas (>=3) as a Risk Factor for Adenomas at Surveillance
Winawer
Van Stolk
Martinez
Bonithon−Kopp
Yang
Avidan
Bertario
0.1 0.2 0.5 1.0 2.0 5.0 10
Relative Risk
Multiple Adenomas (>=3) as a Risk Factor for Advanced Neoplasia at Surveillance
Winawer/Zauber
Van Stolk
Martinez
Bonithon−Kopp
Atkin (CC 1adn)
Atkin (CC >=2 adn)
Atkin (RC 1 adn)
Atkin (RC >=2 adn)
Yang
Noshirwani
Bertario
Nusko
0.1 0.2 0.5 1.0 2.0 5.0 10
Relative Risk
Adenoma Size (>=1.0 cm) as a Risk Factor for Adenomas at Surveillance
Winawer
Van Stolk
Martinez
Bonithon−Kopp
Yang >1cm
Fossi >1cm
Avidan
Bertario 1−2 cm
Bertario >2cm
0.1 0.2 0.5 1.0 2.0 5.0 10
Relative Risk
Adenoma Size (>=1.0 cm) as a Risk Factor for Advanced Neoplasia at Surveillance
Van Stolk
Martinez
Bonithon−Kopp
Atkin CC <1 cm
Atkin CC 1−2 cm
Atkin CC 2cm
Atkin RC < 1 cm
Atkin RC 1−2 cm
Atkin RC > 2cm
Noshirwani
Yang
Bertario 1−2 cm
Bertario > 2 cm
Nusko
0.1 0.2 0.5 1.0 2.0 5.0 10
Relative Risk
Tubulovillous Histology as a Risk Factor for Adenomas at Surveillance
Van Stolk
Martinez
Bonithon−Kopp
Yang
Fossi
Avidan
Bertario
0.1 0.2 0.5 1.0 2.0 5.0 10
Relative Risk
Tubulovillous Adenomas as a Risk Factor for Advanced Neoplasia at Surveillance
Van Stolk
Martinez
Bonithon−Kopp
Atkin CC TUB
Atkin CC TV
Atkin CC V
Atkin RC TUB
Atkin RC TV
Atkin RC V
Yang
Noshirwani
Bertario TV
Loeve TUB
Loeve TV
Loeve V
0.1 0.2 0.5 1.0 2.0 5.0 10
Relative Risk

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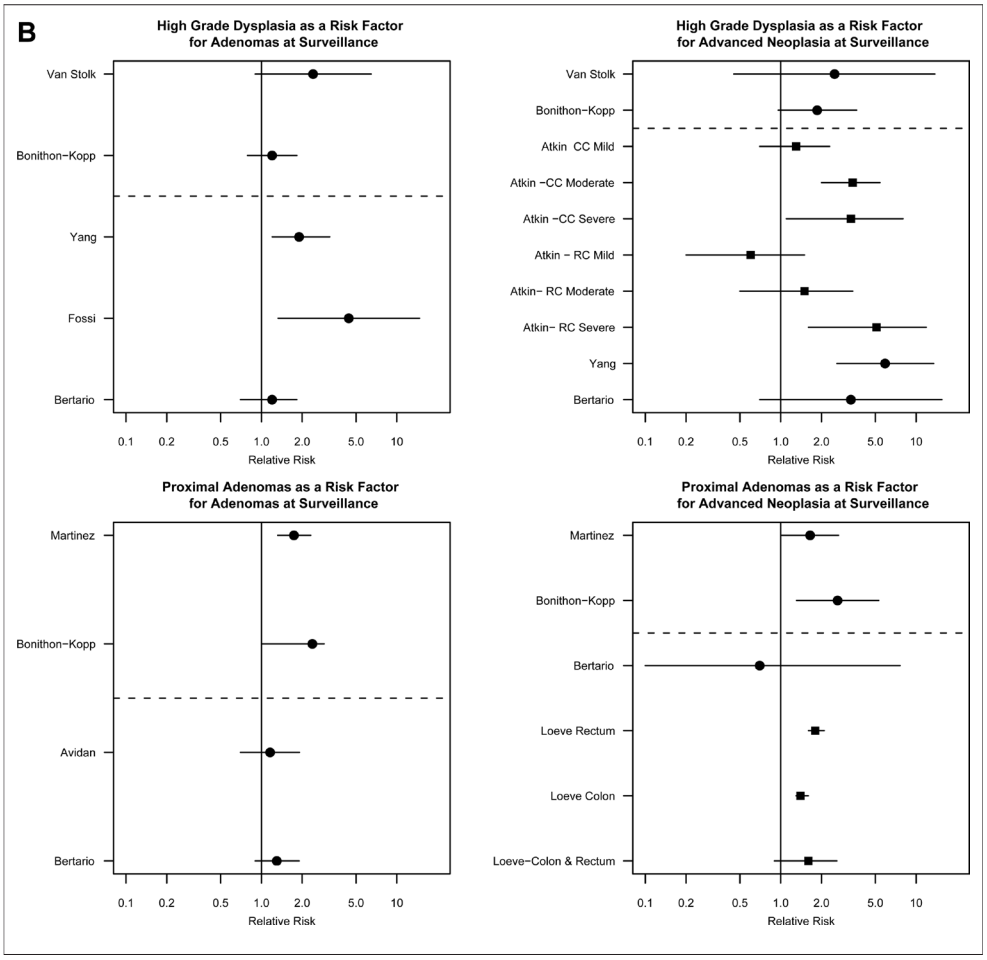

FIGURE **1** Associations between Adenoma Characteristics at Baseline and Subsequent Risk of Adenomas and of Advanced Adenomas or Colorectal Cancer. The dotted line separates the results from the randomized controlled trials of surveillance and chemoprevention from the results of the observational cohort studies. Within the two groupings, the studies are listed by year published. Graphs are presented for the baseline risk factors of adenoma multiplicity (≥3), adenoma size (≥1.0 cm), and adenoma histology (tubulovillous or villous) in **A**, and for high grade dysplasia and for proximal location in **B**. The left column is for the risk with respect to adenomas at surveillance, and the right column is for risk with respect to advanced neoplasia. The studies differ with respect to the classification levels of the risk factors and on the definition of advanced neoplasia. The specification of each study is given in the evidence tables accessible at http://caonline.amcancersoc.org/content/vol56/issue3/. The studies also cover different periods of follow up and use different measures of effect, such as odds ratios (OR), relative risks (RR), hazard ratios (HR), and standardized incidence ratios (SIR), as noted in the evidence tables accessible at http://caonline.amcancersoc.org/content/vol56/issue3/. RR is used on the horizontal axis to represent these different measures of effect. The referent category for the ORs, RRs, and HRs is the lowest risk category. These estimates are denoted by circles. Multivariate estimates are used when available. In two studies,[7,21] SIRs were reported and are denoted by squares. The referent category for the SIR is the general population. Note: Avidan[34] and Noshirwani[31] used number of adenomas, not ≥3 adenomas. RR represents OR, RR, or HR, or standardized incidence ratio as summarized for each study in the evidence tables accessible at http://caonline.amcancersoc.org/content/vol56/issue3/. CC = colon cancer; RC = rectal cancer.

large proportion of cancers were found early; this was probably due in part to inadequate removal of large adenomatous polyps. For example, nine of 19 cancers in the study of Robertson et al were found within 26 months of the initial colonoscopy.[20]

Characteristics of Baseline Adenomas as Predictors of Subsequent Advanced Adenomas

See evidence table (accessible at http://caonline.amcancersoc.org/content/vol56/issue3/) and Figure 1.

Multiplicity

Multiplicity at baseline has been shown to predict subsequent detection of advanced adenomas. Of the RCTs, the National Polyp Study,[25] the European fiber and calcium study,[29]and the pooled analysis of chemoprevention studies[20] showed that multiplicity conferred an increased risk for advanced neoplasia at surveillance. The pooled analysis did not report odds ratios but did report a significant difference in mean number of prior lifetime adenomas at baseline in those with and without advanced neoplasia at surveillance. Neither the wheat bran study described by Martinez[28] nor the chemoprevention study presented by van Stolk[27] noted a significant association between baseline multiplicity and detection of advanced adenoma at follow up. However, 35% of subjects in Martinez's study[28] had prior adenomas, so that prior colonoscopies may have reduced the number of adenomas detected at the index colonoscopy for study accrual. Van Stolk[27] showed that individuals with three or more adenomas at baseline were more likely than those with one or two adenomas at baseline to have an adenoma detected at surveillance (OR = 2.25; 95% CI: 1.20 to 4.21), but found no adenoma characteristic predictive of advanced adenomas at surveillance. She noted, however, that her study had limited power to detect risk factors for advanced neoplasia.

The observational cohort studies also showed that multiplicity was a risk factor for subsequent advanced adenomas and cancer. Atkin followed a cohort of patients that initially had had rectosigmoid adenomas removed but with no further intervention in the colon for an average of 13.8 years. She showed that having two or more rectosigmoid adenomas, compared to one rectosigmoid adenoma at baseline, was associated with an increased risk for subsequent colon cancer but not for subsequent rectal cancer.[7] Noshirwani, et al. reported that the number of adenomas at baseline was related to an increased risk (OR = 1.25; 95% CI: 1.13 to 1.38) for advanced adenomas at surveillance in a cohort from the Cleveland Clinic.[31]

Size

Adenoma size greater than 1 cm also was shown to predict metachronous advanced adenomas in the wheat bran study.[28] However the other four RCTs did not find adenoma size at baseline to be an independent predictor of advanced neoplasia at surveillance. Adenoma size was important in seven of eight of the observational cohort studies assessing advanced neoplasia. Loeve did not present data on adenoma size.[21] In a rigid sigmoidoscopy study, Atkin reported that there was a significant trend ($P < 0.002$) for increased risk of subsequent colon cancer with increasing size of the rectosigmoid adenoma at baseline.[7] The SIR for colon cancer was 1.5 (95% CI: 0.8 to 2.4) in patients with baseline adenomas less than 1 cm in size, increased to SIR = 2.2 (95% CI: 1.1 to 4.0) for 1 to 2 cm adenomas and further increased to SIR = 5.9 (95% CI: 2.8 to 10.6) for adenomas larger than 2 cm. Increasing size of the rectosigmoid adenomas at baseline also showed a significantly increasing trend of an increase in standardized incidence ratio for rectal cancer even though the individual standardized incidence ratios for rectal cancer by adenoma size were not statistically different from the general population risk. Yang, et al., also in a sigmoidoscopy study, demonstrated that larger adenoma size was related to subsequent risk of advanced neoplasia at surveillance with RR = 2.4 (95% CI: 1.3 to 4.6) for size 0.6 to 1.0 compared with size ≤0.5 cm and RR = 4.4 (95% CI: 1.9 to 10.2) for size greater than 1.0 cm at baseline.[30] Noshirwani, et al. demonstrated that a baseline adenoma ≥1 cm compared with less than 1 cm conferred an OR

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of 3.68 for subsequent advanced neoplasia.[31] Bertario, et al. found that patients with adenomas greater than 2 cm compared with ≤2 cm at baseline had a hazard ratio of 4.0 (95% CI: 1.1 to 14.4) for the development of follow-up advanced adenomas.[12] Lieberman, et al., in 5-year follow-up results from the VA Cooperative Study 380, found that the percentage of patients with advanced neoplasia was higher in those with baseline adenomas ≥1.0 cm (2.6%) compared with less than 1.0 cm (0.4%) over 5 years surveillance.[24] Although the majority of studies reported size to be a significant factor, some did not. Neither van Stolk nor Bonithon-Kopp found size to be a significant predictor of metachronous advanced adenomas.[27,29] Incomplete removal of large polyps identified at baseline could be a reason that larger size was a strong predictor of subsequent advanced neoplasia in these studies.

Histology

Histologic type of adenoma at baseline was not a significant predictor of advanced neoplasia in the randomized trials but was for several of the observational cohorts. Histology is a particularly difficult predictor to evaluate because of the somewhat subjective nature of classifying tubular, tubulovillous, and villous adenomas.[45] Atkin, et al., in a rigid sigmoidoscopy study, demonstrated that tubulovillous histology at baseline was associated with an SIR = 3.8 (95% CI: 2.2 to 6.0), and villous histology had an SIR = 5.0 (95% CI: 2.2 to 9.9) for the detection of subsequent colon cancer.[7] Histology at baseline was also an important predictor for subsequent rectal cancer risk in this study. In another sigmoidoscopy study, Yang, et al. reported that villous or tubulovillous histology at baseline conferred a relative risk of 8.34 (95% CI: 3 to 16.0) for the detection of advanced neoplasms (rectal cancer, or adenoma with severe dysplasia) at follow up.[30] Loeve reported a significant trend for increasing risk of colorectal cancer at surveillance in relationship to increasing villous component or carcinoma in situ compared with tubular histology.[21]

High-grade dysplasia is related to larger adenoma size and villous component at baseline and is an important predictor for subsequent advanced neoplasia in three of the observational cohort studies.[7,24,30] By definition, all adenomas have some level of dysplasia. In the past, dysplasia has been classified as mild, moderate, severe, or carcinoma in situ. Currently, severe dysplasia or carcinoma in situ are considered the equivalent of high-grade dysplasia, and mild or moderate dysplasia are considered the equivalent of low-grade dysplasia. For the purposes of this analysis, wherever possible, the risks are assessed for high-grade and low-grade dysplasia. Atkin, et al. found increasing degree of dysplasia was associated with an increasing risk of subsequent colon cancer with a standardized incidence ratio of 3.3 (95% CI: 1.1 to 8.0) for severe dysplasia in baseline adenomas.[7] Yang reported odds ratios of 5.9 (95% CI: 2.6 to 13.5) and 14.4 (95% CI: 5.0 to 41.4), respectively, for the development of subsequent advanced neoplasia (rectal cancer or severe dysplasia) in patients with moderate and severe dysplasia at baseline.[30] Lieberman, et al., in the VA Cooperative Study, determined that 10.9% of patients with high-grade dysplasia in adenomas of any size at baseline had advanced neoplasia over the 5-year surveillance period compared with 0.6% in those with tubular adenomas less than 1.0 cm lacking high-grade dysplasia.[24]

Location

Martinez, et al. reported that a proximal adenoma at baseline was associated with an increased risk of subsequent advanced adenomas. The odds ratio was 1.65 (95% CI: 1.02 to 2.67) for baseline proximal adenomas only versus distal adenomas only, and OR = 2.69 (95% CI: 1.34 to 5.42) for proximal and distal adenomas versus distal adenomas only at baseline.[28] Similarly, Bonithon-Kopp, et al. reported an odds ratio of 2.63 (90% CI: 1.31 to 5.3) for subsequent advanced neoplasia for patients with proximal compared with no proximal location of baseline adenomas.[29] In the observational cohort study of Loeve[21] using large registry databases, the risk of colorectal

cancer at surveillance was slightly lower for patients with colon adenomas at baseline than rectal adenomas.

Other Risk Factors: Patient Age, Sex, History of Polyps, and Family History of Colorectal Carcinoma

In their RCTs, Martinez and Bonithon-Kopp reported an increasing risk of subsequent neoplasia with increasing age.[28,29] Age was frequently employed as a control variable in the analyses without an explicit risk factor presented for the age effect. Martinez and Bonithon-Kopp reported an increased risk for men for advanced neoplasia at surveillance.[28,29] Sex was also frequently employed as a control variable in the analyses without an explicit risk factor presented for the sex effect.

Both Martinez and Bonithon-Kopp noted that a history of polyps before the baseline adenoma was associated with an increased risk for advanced neoplasia at surveillance.[28,29] Although it is not always possible to determine whether prior polyps are adenomatous polyps, the presence of prior polyps can be considered as an additional risk factor. The effect of prior adenomas or other polyps on subsequent risk was not considered in all studies. When noted in the reviewed studies, the percentage of patients in a study with prior adenomas or other prior polyps is included in the evidence table (accessible at http://caonline.amcancersoc.org/content/vol56/issue3/).

Family history of colorectal cancer and adenomas at a young age[46] is an established risk factor for the development of colorectal cancer.[47–49] However, few studies have specifically addressed the relationship between family history and metachronous advanced adenomas in postpolypectomy patients. The National Polyp Study demonstrated that a family history of colorectal cancer in patients ≥60 years of age predicted a 4.8-fold increased risk of advanced adenomas at follow up.[26] Fossi noted family history of colorectal cancer in a first-degree relative as a risk factor for adenomas at surveillance, but the study did not report on risk factors for advanced adenomas at surveillance.[32] As noted above, Martinez and Bonithon-Kopp both reported proximal adenomas at baseline as predictors of subsequent advanced neoplasia.[28,29] Proximal adenomas are associated with family history of colorectal cancer.[49] It is possible that these studies might also have had an increased risk for advanced adenoma because of the association of family history of colorectal carcinoma with proximal adenomas.

SUMMARY OF BASELINE PREDICTORS

The totality of evidence suggests that multiplicity (≥3 adenomas), size (≥1 cm), villous features, and high-grade dysplasia are predictors of future advanced adenomas or cancers. Family history and proximal location may also predict metachronous advanced adenomas but have not been well studied. Analysis of the relative importance of each of these predictors is complicated by their interrelationships. Consequently, multivariate analysis for some studies may find that size and histology[45] are the most important, whereas others may report that multiplicity is the most important.

There is a consensus among many of the studies that the group at lower risk for subsequent advanced adenomas has only one or two adenomas, all less than 1 cm in size, with no high-grade dysplasia or villous features. Risk for colon cancer in such low-risk patients, over an average of 14 years, has been shown in a rigid sigmoidoscopy polypectomy study to be similar to the average risk population.[7]

In colonoscopy studies, patients have been followed only 5 to 6 years after colonoscopic polypectomy to assess their subsequent risk for neoplasia.[24,25] Sigmoidoscopic polypectomy without colonoscopic assessment is insufficient to establish colonoscopic surveillance intervals. In the Atkin study, colon risk was assessed in an anatomic area where polypectomy was not performed (ie, above the rectosigmoid).[7] Postpolypectomy surveillance guidelines should ideally be based on colonoscopic follow up of patients who have had colonoscopic polypectomy. Based on the available evidence, we can project that apparently low-risk patients can wait 5 and possibly 10 years for repeat colonos-

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copy. However, further evaluation of this low-risk group is required to confirm the safety of these intervals.

For rarer events, such as colorectal cancer at surveillance and even for adenomas in the smaller studies, the confidence intervals on colorectal cancer or advanced neoplasia may be relatively wide. Consequently, a nonstatistically significant result does not rule out that this factor has no impact on risk for surveillance findings.

DISCUSSION

These guidelines are based on all of the available evidence, clinical experience, knowledge of the adenoma-carcinoma sequence, and expert opinion. They are intended to be used by clinicians as a guide in their approach to postpolypectomy surveillance, taking into consideration clinical judgment in patient comorbidities, patient preferences, and family history. The differences between these guidelines and prior ones are shown in Table 1. The detailed evidence for these guidelines is presented in the literature review summarized by the evidence tables accessible at http://caonline.amcancersoc.org/content/vol56/issue3/ and in Figure 1.

There is strong evidence that the adenoma cohort can be stratified according to the risk of development of subsequent advanced adenomas. Recommendations for surveillance intervals in persons with multiple adenomas and those with advanced adenomas are based primarily on the National Polyp Study,[25] a randomized controlled trial, and observational cohort studies. Recommendations in the low-risk group of one to two small tubular adenomas are based on the low incidence of advanced adenomas in observational cohort studies and the National Polyp Study[25] over 3- to 6-year intervals and the observation by Atkin, et al. that persons with small tubular adenomas are not at increased risk of developing colorectal cancer.[7] In the opinion of the panel, the data from observation of cohort studies supports an interval of at least 5 years in this low-risk group; however, the panel reasoned that based on the Atkin data, informed physicians and their patients could conclude that a 10-year interval, similar to that used in the average-risk population, would also be acceptable. The recommendation to perform short interval follow up in patients with 10 or more adenomas is based on the increased probability of missed lesions in patients with numerous adenomas. The recommendation to perform very short interval follow up in patients with large sessile polyps removed piecemeal is the repeated observation that a significant fraction of these polyps are incompletely removed by the initial polypectomy. Recommended intervals in HNPCC are based on the known rapid transformation through the adenoma carcinoma sequence in these patients.[50]

The present collaborative effort between the US Multi-Society Task Force on Colorectal Cancer and the ACS was based on several considerations. The gradual increase in screening and the marked increase in screening colonoscopy are producing a large subset of the population that requires surveillance based on adenoma detection. Both societies felt the need to update the guidelines for the follow up of these patients, according to the latest evidence. Recent surveys have shown that 50% of endoscopists are not following previously published guidelines for postpolypectomy surveillance.[51,52] It was felt that a consensus by the two organizations would strengthen the recommendations and increase their utilization.

From the 1970s to the 1990s, annual follow-up colonoscopy was common practice after polypectomy, and there were no guidelines available addressing how clinicians should best follow these patients. In 1993, a report from the National Polyp Study demonstrated that it was safe to defer the first follow-up examination for 3 years.[25] This evidence, along with the knowledge of the long natural history of the adenoma-carcinoma progression, led to guidelines in 1997 that recommended a 3-year interval for the first follow-up examination after removal of adenomas.[15,16] Practice began to evolve along the lines of this evidence. Guidelines have been used in the courts of law as indicating the standard of practice.[53]

Recent guidelines have introduced the concept of risk stratification of patients at the time

of polypectomy into those more likely or less likely to develop subsequent serious neoplasia.[13] In addition, the concept of the advanced adenoma as a surrogate biological indicator of cancer risk has been adopted.[36] Colorectal cancer would be a more ideal outcome measure. However, the advanced adenoma was adopted as an early outcome measure of efficacy because a much longer period of time would be required for conclusions to be drawn if cancer were used as the outcome measure. This reasoning is supported by several studies that have demonstrated the relationship between advanced adenomas and cancer.[45,54,55] A uniform definition of the advanced adenoma has not yet been clearly established, but most include adenomas with size ≥1 cm, any villous histology, or high-grade dysplasia.

Several studies have examined factors that could predict future risk of advanced adenomas, including number, size, histology, and location of baseline adenomas, as well as patient age and family history of colorectal cancer. Most of the studies that assessed risk factors for advanced adenomas at surveillance were either randomized controlled trials of surveillance,[25] chemoprevention trials,[20,27–29] prospective surveillance studies,[24] or registry-based observational cohort studies of patients returning for surveillance with less structured follow up outside the context of a clinical trial.[7,12,21,30,31,33,35] The most consistent evidence for predicting subsequent advanced adenomas indicates that multiplicity, size, villous histology, and high-grade dysplasia are the important factors at baseline. Based on these factors, patients can be stratified at the time of colonoscopy into lower or higher risk for subsequent advanced adenomas. The strongest studies for evaluating predictive factors for future neoplasia after polypectomy are those specifically designed as postpolypectomy surveillance studies such as the National Polyp Study. Chemoprevention randomized trials were designed to assess the drug intervention effect with less of an emphasis on determining optimal surveillance intervals.

Patients who have had a polypectomy and long-term surveillance have been shown to have a reduced incidence of colorectal cancer.[5–12] When one separates out the effect of initial polypectomy from the subsequent surveillance, modeling has demonstrated that more than 90% of the reduced incidence over the first 5 to 6 years is the result of the initial polypectomy. However, there is a subgroup that can be identified as having a higher risk of subsequent cancer by using the advanced adenoma as a surrogate marker.[56] These observations support the concept of stratifying patients by baseline factors so that the group at increased risk can be identified for more intensive surveillance and the group at lower risk can be identified for less intensive surveillance. Reduction in the intensity of surveillance could free up endoscopic resources that could be shifted to screening and diagnosis, thereby increasing the benefit and reducing the procedural risk.

Use of fecal occult blood testing (FOBT) after colonoscopy in postpolypectomy patients has been reported to be a widespread practice (38% of patients had FOBT after adenoma removal at colonoscopy).[57] The National Polyp Study has demonstrated that use of FOBT after colonoscopy results in a substantial number of unnecessary colonoscopies: 77% of colonoscopies performed to evaluate positive surveillance FOBT results detected no advanced adenomas or cancer (ie, the positive predictive value was 23%).[58] In a recent report by Bampton, et al. of 785 patients having had a recent surveillance colonoscopy, the positive predictive value for an immunochemical FOBT was 27%.[59] This was in a high-risk cohort comprised of patients with history of colonic neoplasia or with strong family history. A lower positive predictive value would be expected in a lower-risk population. The possible benefit of FOBT in patients having surveillance colonoscopies needs further study, but with the present available evidence this should be discouraged.

In the present guidelines, recommendations for the lower-risk group are intentionally flexible because follow-up colonoscopy studies are limited to 5 to 6 years.[24,25] Some physicians and patients may elect to have a follow-up colonoscopy at 5 years because they wish to be assured that future risk has been reduced below that of the average-risk population. Others may

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feel confident that this risk has already been reduced below that of the general population by adequate clearing of the colon and would be satisfied with either a 10-year follow-up colonoscopy or choosing other screening options currently recommended for individuals at average risk.[14]

Risk stratification and recommended follow-up intervals are based on the presumption that a high-quality colonoscopy was performed at baseline. However, variable colonoscopic miss rates for adenomas and cancer have been shown.[5,20,39-42,60-62]

This variability in colonoscopic baseline quality could translate into either a lower rate of subsequent cancers detected during surveillance as in the National Polyp Study[5,62] or a higher rate as seen by Robertson, et al. and others.[20,39,61] For example, in the NPS, if the baseline colonoscopy did not clear the colon with high confidence (excellent preparation, complete polypectomy), the exam was repeated before entering the patient into the surveillance program. Repeat exams were required in 13% of the cases.[25] Such rigor contributed to a marked reduction in colorectal cancer incidence in the NPS, which was not observed in other studies.[20,39,61] In the Australian and Japanese studies,[60,62] the low miss rates were calculated only from cases in which the cecum was intubated. In one study of "missed cancers,"[39] failure to intubate the cecum accounted for some undetected cancers.

The quality of the baseline examination can be evaluated to some extent by the number of cancers detected earlier versus later in a surveillance program. Thus, the major benefit of the baseline colonoscopic polypectomy rests on the quality of that examination.[37,38] The concern by clinicians of missed cancers can be assuaged by high-quality baseline performance of colonoscopy. Protection can never be 100%, but it is high (76% to 90% colorectal cancer incidence reduction) with high confidence examination.[5,63]

There was insufficient evidence to include family history in the guidelines as a predictor of metachronous advanced adenomas. Clearly, however, family history of colorectal cancer in a close relative does increase the risk of colorectal cancer in other relatives and needs further study in the postpolypectomy setting.[47–49] Issues such as this must be considered on an individual basis when clinicians are determining appropriate follow up.

Patients with a family history indicating HNPCC require special screening and surveillance.[13,15,49] HNPCC is an autosomal dominant inherited cancer syndrome which accounts for 1% to 5% of colorectal cancer cases and is caused by germline mutations in one of five mismatch repair genes. The mean age for colorectal cancer development in HNPCC is 44 years. Cancers tend to be right sided and often are poorly differentiated, mucus-producing tumors with intense lymphocytic infiltrates. Tumors demonstrate microsatellite instability (MSI) and immunostaining is often negative for one of the mismatch repair gene products. There are no clinical criteria that are perfectly sensitive for HNPCC. The modified Bethesda criteria perform best in this regard.[64] HNPCC should be suspected when colorectal cancer or other tumors with relative specificity for HNPCC (endometrial, ovarian, small bowel, ureter, or renal pelvis) occur in younger people, when multiple relatives and generations are affected, or when tumor location and histology are suggestive. Potentially affected persons can be screened by testing their tumors for microsatellite instability or for mismatch repair gene products by immunostaining. Genetic testing is used when these screening tests are positive or when the clinical presentation and family history are very strongly suggestive. Tumors in HNPCC move through the adenoma-carcinoma sequence more rapidly than sporadic tumors.[50] Definite or potential gene carriers are screened by colonoscopy every 2 years beginning at age 20 to 25 years until age 40 years, and then annually.[13] Surveillance recommendations are essentially the same as screening. The colon must be carefully cleared and complete polypectomy is essential, particularly for advanced adenomas. Patients who develop advanced adenomas and proven gene carriers can be offered prophylactic

subtotal colectomy followed by annual proctoscopy and polypectomy.

Other issues evolving in the literature that require further study and may affect future guidelines as data matures include different recommendations for men and for women by age.[65] Given the evolving nature of guidelines, it is important that physicians and patients remain in contact so that surveillance practices will reflect changes in guidelines.

Management of patients with hyperplastic polyps only was omitted from prior guidelines. There is no evidence that patients with small distally located hyperplastic polyps have an increased risk for colorectal cancer, and they should therefore be rescreened as appropriate for average-risk patients.[66,67] The present guidelines state this explicitly. It has been shown recently, however, that hyperplastic polyps are not a homogenous histological category, and there is accumulating evidence from molecular genetic studies that some histological variants of hyperplastic polyps may evolve into a unique type of adenoma called a serrated adenoma that resembles a hyperplastic polyp with dysplasia.[68] This type of adenoma has in turn been linked to the ultimate development of sporadic MSI adenocarcinoma. This form of colonic adenocarcinoma shares with HNPCC the genetic attribute (in this case, acquired) of microsatellite instability (sporadic MSI cancers) due to mismatch repair deficiency. Hyperplastic polyps at risk for such a progression exhibit atypical architectural and cytologic features, are often large and sessile, and are usually proximally located. Other terms for these hyperplastic polyp variants are sessile serrated adenoma or serrated polyp with abnormal proliferation. Some authors have suggested that complete removal and surveillance, as for typical adenomas, may be warranted in these cases.[69,70]

All endoscopists must remain alert to the syndrome of hyperplastic polyposis. Hyperplastic polyposis was defined by Burt and Jass for the World Health Organization International Classification of Tumors as: (1) at least five histologically diagnosed hyperplastic polyps proximal to the sigmoid colon, of which two are greater than 1 cm in diameter; or (2) any number of hyperplastic polyps occurring proximal to the sigmoid colon in an individual who has a first-degree relative with hyperplastic polyposis; or (3) greater than 30 hyperplastic polyps of any size distributed throughout the colon.[71] Studies have found an increased risk of colorectal cancer in these patients.[72,73] The pathway may be through the serrated adenoma.[69,74,75] The magnitude of the increased risk has not been determined. A recent case series of 15 patients found no cancer developed within 3 years of follow up.[76] The optimal management of hyperplastic polyposis has not yet been defined and requires further study.

Technological advances such as computed tomography (CT) colonography (also known as virtual colonoscopy, which uses CT scan technology), chromoendoscopy (endoscopy with dye spraying of the mucosa), narrow-band imaging (a high-resolution endoscopic technique that enhances the fine structure of the mucosal surface without dye), and magnification endoscopy (real-time magnification of endoscopic images) may one day be shown to be important in postpolypectomy surveillance.[77–81] Some of these techniques may have a special role in detecting flat adenomas.[82,83] However, at this time there is insufficient evidence that any of these techniques should be part of routine postpolypectomy surveillance.

In summary, guidelines are dynamic and based on the evidence currently in the literature, understanding of the adenoma carcinoma sequence, and expert opinion. Guidelines must be updated as new evidence becomes available. The committee identified a number of areas of uncertainty and considers the following to be among the important questions for further study.

QUESTIONS TO BE ADDRESSED

1. What are the reasons that guidelines are not more widely followed?
2. How can adherence to quality control indicators at baseline colonoscopy be encouraged to reduce the miss rate of advanced adenomas and colorectal cancers?

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3. Will emerging studies with longer colonoscopy follow up support the safety of lengthening surveillance intervals?

4. What is the appropriate management and surveillance of the hyperplastic polyposis syndrome?

5. What is the appropriate surveillance of patients who have had an adenoma removed in piecemeal fashion?

6. Which definition of advanced adenoma is most strongly associated with subsequent cancer?

7. In the setting of postpolypectomy surveillance, what is the role of family history in predicting advanced adenomas and colorectal cancer?

8. What roles will chromoendoscopy, magnification endoscopy, narrow-band imaging, and CT colonography play in postpolypectomy surveillance?

9. How can molecular genetic information help to stratify risk in patients with adenomatous polyps?

10. How can access to colorectal cancer screening and appropriate surveillance be increased?

11. What is the utility of guaiac-based, or immunochemical, FOBT in postpolypectomy surveillance?

12. What is the utility of stool DNA mutation testing in postpolypectomy surveillance?

13. What is the importance of detecting flat adenomas?

14. What is the importance of detecting serrated adenomas?

15. How do new insights in links between serrated polyps and MSI cancers impact surveillance practices?

16. What surveillance guidelines are appropriate for patients with atypical hyperplastic polyps—particularly if large, proximally located, or multiple—and for patients with serrated adenomas?

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Guidelines for Colonoscopy Surveillance after Cancer Resection: A Consensus Update by the American Cancer Society and US Multi-Society Task Force on Colorectal Cancer*,†

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(continued next page)

ABSTRACT Patients with resected colorectal cancer are at risk for recurrent cancer and metachronous neoplasms in the colon. This joint update of guidelines by the American Cancer Society (ACS) and US Multi-Society Task Force on Colorectal Cancer addresses only the use of endoscopy in the surveillance of these patients. Patients with endoscopically resected Stage I colorectal cancer, surgically resected Stage II and III cancers, and Stage IV cancer resected for cure (isolated hepatic or pulmonary metastasis) are candidates for endoscopic surveillance. The colorectum should be carefully cleared of synchronous neoplasia in the perioperative period. In nonobstructed colons, colonoscopy should be performed preoperatively. In obstructed colons, double contrast barium enema or computed tomography colonography should be done preoperatively, and colonoscopy should be performed 3 to 6 months after surgery. These steps complete the process of clearing synchronous disease. After clearing for synchronous disease, another colonoscopy should be performed in 1 year to look for metachronous lesions. This recommendation is based on reports of a high incidence of apparently metachronous second cancers in the first 2 years after resection. If the examination at 1 year is normal, then the interval before the next subsequent examination should be 3 years. If that colonoscopy is normal, then the interval before the next subsequent examination should be 5 years. Shorter intervals may be indicated by associated adenoma findings (see Postpolypectomy Surveillance Guideline). Shorter intervals are also indicated if the patient's age, family history, or tumor testing indicate definite or probable hereditary nonpolyposis colorectal cancer. Patients undergoing low anterior resection of rectal cancer generally have higher rates of local cancer recurrence, compared with those with colon cancer. Although effectiveness is not proven, performance of endoscopic ultrasound or flexible sigmoidoscopy at 3- to 6-month intervals for the first 2 years after resection can be considered for the purpose of detecting a surgically curable recurrence of the original rectal cancer. (*CA Cancer J Clin 2006;56:160–167.*) *© American Cancer Society, Inc., 2006.*

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INTRODUCTION

Recommendations (Table 1) on the use of surveillance colonoscopy after resection of colorectal cancer were produced jointly by the US Multi-Society Task Force on Colorectal Cancer and the American Cancer Society (ACS). They constitute the updated recommendations of both organizations. The rationale for combined guidelines by organizations is discussed in the accompanying joint recommendations on postpolypectomy surveillance. These guidelines were endorsed by the Colorectal Cancer Advisory Committee of the ACS and by the governing boards of the American College of Gastroenterology, the American Gastroenterological Association, and the American Society for Gastrointestinal Endoscopy.

Table 2 summarizes the differences in these guidelines from previous guidelines on postcancer resection surveillance colonoscopy.

METHODOLOGY AND LITERATURE SEARCH

The literature search sought to identify randomized controlled trials and cohort studies in which patients with resected colorectal cancer and perioperative clearing of synchronous neoplasia by colonoscopy were followed to detect recurrent and/or metachronous neoplasms.

We searched the medical literature using MEDLINE (1966-January 17, 2005), the Cochrane Database of Systematic Reviews (fourth quarter 2004 update), and the Database of Abstracts of Reviews of Effects (fourth quarter 2004 update). In MEDLINE, subject headings for colorectal neoplasms were combined with subheadings and keywords for "surgery," "resection," "colonoscopy," "surveillance," and "follow-up" to identify relevant citations. Only studies published in the English language were included. Surveillance studies in patients with inflammatory bowel disease or hereditary nonpolyposis colorectal cancer (HNPCC) were specifically excluded. Keyword searches were also performed in the Cochrane Database of Systematic Reviews and the Database of Abstracts of Reviews of Effects to identify any additional systematic reviews. In addition, a manual search was performed using references from retrieved reports, review articles, guidelines, meta-analyses, editorials, and textbooks of gastroenterology.

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TABLE **1** Postcancer Resection Surveillance Colonoscopy Recommendations

1. **Patients with colon and rectal cancer should undergo high quality perioperative clearing.** In the case of nonobstructing tumors, this can be done by preoperative colonoscopy. In the case of obstructing colon cancers, computed tomography colonography with intravenous contrast or double contrast barium enema can be used to detect neoplasms in the proximal colon. In these cases, a colonoscopy to clear the colon of synchronous disease should be considered 3 to 6 months after the resection if no unresectable metastases are found during surgery. Alternatively, colonoscopy can be performed intraoperatively.
2. **Patients undergoing curative resection for colon or rectal cancer should undergo a colonoscopy 1 year after the resection (or 1 year following the performance of the colonoscopy that was performed to clear the colon of synchronous disease).** This colonoscopy at 1 year is in addition to the perioperative colonoscopy for synchronous tumors.
3. **If the examination performed at 1 year is normal, then the interval before the next subsequent examination should be 3 years.** If that colonoscopy is normal, then the interval before the next subsequent examination should be 5 years.
4. **Following the examination at 1 year, the intervals before subsequent examinations may be shortened if there is evidence of hereditary nonpolyposis colorectal cancer or if adenoma findings warrant earlier colonoscopy.**[1]
5. **Periodic examination of the rectum for the purpose of identifying local recurrence, usually performed at 3- to 6-month intervals for the first 2 or 3 years, may be considered after low anterior resection of rectal cancer.** The techniques utilized are typically rigid proctoscopy, flexible proctoscopy, or rectal endoscopic ultrasound. These examinations are independent of the colonoscopic examinations described above for detection of metachronous disease.

TABLE **2** Differences between Current and Previous Guidelines on Postcancer Resection Surveillance Colonoscopy

In addition to careful perioperative clearing of the colorectum for synchronous lesions, a colonoscopy is recommended 1 year after surgical resection because of high yields of detecting early second, apparently metachronous cancers.
Clinicians can consider periodic examination of the rectum for the purpose of identifying local recurrence after low anterior resection of rectal cancer.

We excluded articles if there was no evidence of perioperative colonoscopic clearing or if a modality other than colonoscopy (flexible sigmoidoscopy, barium enema) was used for perioperative clearing.

A total of 66 studies were retrieved for detailed evaluation, and 43 were excluded: 26 because of incomplete perioperative colonoscopic clearing or because this was accomplished with modalities other than colonoscopy, 13 did not pertain to the focus of our paper, three were reports of work in progress that were published in final form in other studies included in our analysis, and one reported the preliminary results of an ongoing trial. The remaining 23 studies were included in our analysis.[2–24]

Evidence tables were created to summarize the studies and were circulated to members of the US Multi-Society Task Force and the ACS Colorectal Cancer Advisory Committee. The evidence was reviewed and recommendations developed at a joint meeting.

DISCUSSION OF EVIDENCE AND RATIONALE FOR THE RECOMMENDATIONS

Limitations in the Selected Studies

Some limitations were identified in interpreting the selected studies on postcancer surveillance colonoscopy literature.[2–24] For example, the term "metachronous cancer" had variable definitions. In some instances, it was based on the site of tumor appearance within the colon, and in others it was based on time after resection of the initial primary. Many studies made no mention of whether patients may have had hereditary nonpolyposis colorectal cancer. In some cohorts, there was incomplete follow up of patients. Surveillance intervals were different across studies. Some studies did not clearly separate metachronous tumors from anastomotic recurrences or anastomotic from local or regional recurrences. In some cases, there was also failure to report the stage of metachronous cancers and whether or not they were resectable for cure at the time they were diagnosed. In some studies, it was not clear whether colonoscopies were routine procedures in asymptomatic surveillance patients versus diagnostic procedures based on symptoms or laboratory findings. Colonoscopy completion rates and complication rates were commonly not reported, and there was also frequently lack of information on mortality rates. Despite these limitations, a number of clinically relevant trends are evident regarding colorectal cancer recurrence, metachronous cancer, and the utility of surveillance procedures in patients with resected colorectal cancer.

Candidates for Postcancer Resection Surveillance Colonoscopy

In general, patients who undergo surgical resection of Stage I, II, or III colon and rectal cancers, or curative-intent resection of Stage IV cancers are candidates for surveillance colonoscopy. Patients who undergo curative endoscopic resection of Stage I colon cancers are also candidates for surveillance colonoscopy. Patients with Stage IV colon or rectal cancer that is unresectable for cure are generally not candidates for surveillance colonoscopy because their chance of survival from their primary cancer is low, and the risks of surveillance outweigh any potential benefit.

Goals of Surveillance: Detection of Recurrent Cancer versus Metachronous Cancers and Adenomas

There are two fundamental goals of surveillance of patients with resected colon or rectal cancer. One goal is the detection of early recurrences of the initial primary cancer at a stage that would allow curative treatment. The second goal is detection of metachronous colorectal neoplasms. In regard to detection of recurrences of the initial primary cancer, serial measurements of carcinoembryonic antigen are widely used.[25] In addition, recent meta-analyses of randomized controlled trials suggest that annual chest x-rays and computed tomography (CT) scans of the liver can improve survival from the original primary cancer by early detection of surgically curable recurrences.[26] The roles of serial performance of serum carcinoembryonic antigen measurements, serial chest x-rays,

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and CT scans of the liver are not reviewed here. Neither individual randomized controlled trials of intensive surveillance with colonoscopy[20] nor meta-analyses of these trials[26] have demonstrated a survival benefit from the original primary tumor by performing colonoscopy at annual or shorter intervals. The failure of surveillance endoscopic exams to improve survival from recurrent colorectal cancer appears to result from relatively low rates of anastomotic or intraluminal recurrence and the observation that anastomotic or intraluminal recurrences are generally associated with intraabdominal or pelvic disease that is unresectable for cure.[2–24,26,27] In summary, performance of annual colonoscopy for the purpose of detecting recurrent disease does not have an established survival benefit for patients with colorectal cancer. (However, as noted below, there is a rationale for surveillance of the rectum after resection of rectal cancer for the detection of local recurrence.) The primary goal of surveillance colonoscopy after resection of colorectal cancer is detection of metachronous neoplasms.

Distinguishing Rectal Cancer versus Colon Cancer Follow Up

Although there is no established benefit from endoscopic surveillance for the purpose of detecting early recurrences of the original cancer, in clinical practice many clinicians distinguish between rectal and colon cancer in this regard. The distinction is based on differences in the rates of local recurrence of rectal versus colon cancer. Specifically, in the case of colon cancer, recurrence at the anastomosis occurs in only 2% to 4% of patients.[2–24] Because the overwhelming majority of patients with endoscopically detected anastomotic recurrences in the colon are unresectable for cure, surveillance colonoscopy for this purpose generally should not be undertaken. On the other hand, local recurrence rates of rectal cancer can be 10 or more times higher.[28–33]

High recurrence rates of rectal cancer are partly a function of surgical technique and volume.[28–33] Specifically, recurrence rates below 10% have been consistently reported when patients are operated on by a technique called total mesorectal excision.[34–36] This technique involves sharp dissection of the rectum and its surrounding adventitia along the first plane outside the adventitia (the mesorectal fascia).[35,36] The technique can be performed using either an open or laparoscopic-assisted approach[37–40] and has been reported to allow higher rates of successful low anterior resection[40] and lower rates of postoperative sexual dysfunction in men.[41]

Local recurrence rates of rectal cancer can also be reduced by administration of chemotherapy and radiation therapy,[34] which have been most effectively administered in the neoadjuvant (preoperative) setting to patients with locally advanced disease. Patients with rectal cancer typically undergo preoperative staging, either by endoscopic ultrasound[42–44] or magnetic resonance imaging,[45–48] followed by neoadjuvant chemoradiation in selected patients.[49] The combination of neoadjuvant chemoradiation and resection by surgeons trained in total mesorectal excision has resulted in very low recurrence rates for rectal cancer.[34] Because local recurrence rates for rectal cancer across the United States are generally higher than those achieved in series utilizing total mesorectal excision, there is a rationale for performing periodic examinations of the rectum by rigid or flexible proctoscopy or endoscopic ultrasound. These techniques have not been shown to improve survival, and the only rationale for their use is high rates of local recurrence.

When colon or rectal cancer is resected endoscopically and surgical resection is not planned because of favorable histology[50] and/or increased surgical risk, a follow-up endoscopic examination to inspect and biopsy the resection site is reasonable.[51] The follow-up examination is considered standard in the case of a sessile malignant polyp removed by piecemeal resection.[1] These examinations are typically performed 3 to 6 months after the initial endoscopic resection.

Detection of Metachronous Neoplasms

A second potential benefit of surveillance colonoscopy is the detection of metachronous cancers at a surgically curable stage, as well as the prevention of metachronous cancers via

TABLE **3** Metachronous Cancers in Postcancer Resection Surveillance Colonoscopy Studies

Study	N	Colonoscopies	Metachronous CRCs (all)	Metachronous CRCs (within 24 months)	Dukes' A or B	Number Asymptomatic	Reoperation for Cure
Barillari[2]	481		12	6*	9	6†	7
Barrier[3]	61‡		0				
Carlsson[4]	129	546	1	0	NS	NS	NS
Castells[5]	199		0				
Chen[6]	231		4	0	NS	4	4
Eckardt[7]	212		0				
Granqvist[8]	390	600	12	7	5§	6§	10
Green[9]	3278		42	24	23	NS	NS
Juhl[10]	133	316	4	0	4	4	4
Khoury[11]	389	3889	2	1	NS	NS	NS
Kjeldsen[12]	597		10	NS	NS	8	8
Kronborg[13]	239	710	4	3	4	NS	4
Makela[14]	106		1	NS	NS	NS	1
McFarland[15]	74	237	0				
Obrand[16]	444		0				
Ohlsson[17]	53¶		0				
Patchett[18]	132		2	NS	NS	0	NS
Pietra[19]	207		1	NS	NS	NS	NS
Schoemaker[20]	325	733	8	5	5	1	NS
Skaife[21]	611	609**	5	1	NS	NS	NS
Stigliano[22]	322		5	0	NS	NS	NS
Togashi[23]	341	1570	22	9	17	NS	22
Weber[24]	75	197	2	1	2	NS	2
Total	9029	9407	137	57	69	29	62

*Paper states "more than one half" arose in first 24 months.
†Paper reports 46 combined local recurrences with metachronous tumors, of which 22 were asymptomatic; number calculated assumes similar proportion for metachronous cancers.
‡Subgroup who underwent perioperative colonoscopy.
§Paper reports 26 combined local recurrences with metachronous tumors, of which 10 were Dukes' A or B and 14 were asymptomatic; numbers calculated assume similar proportion for metachronous cancers.
¶Intensive surveillance subgroup (control group did not undergo routine colonoscopy).
**Two patients underwent barium enema for completion of incomplete colonoscopy.

identification and removal of adenomatous polyps. The incidence of metachronous cancers, the timing at which metachronous cancers occur, and the stage of these cancers at presentation or identification by surveillance colonoscopy should determine the optimal intervals for performance of surveillance colonoscopy directed toward metachronous disease. The evidence from published studies of postcancer resection surveillance in colonoscopy was reviewed to determine what these rates and timing of metachronous cancers are (Table 3). Limitations in interpretation of this literature were described above.

From 2% to 7% of patients with colorectal cancer have one or more synchronous cancers in the colon and rectum at the time of initial diagnosis.[3,4,13,24,52,53] From a practical perspective, it is impossible to differentiate whether apparent metachronous cancers appearing in the interval shortly after resection of colorectal cancer are true metachronous lesions or missed synchronous lesions. Provided that appropriate clearing of the colon is achieved in the perioperative period, all subsequently identified cancers are, for practical purposes, metachronous lesions.

Among 23 studies in which patients underwent perioperative clearing by colonoscopy, there were 9,029 patients in whom 137 apparent metachronous cancers developed.[2–24] Among studies in which the number of colonoscopies performed could be determined, 9,407 colonoscopies were performed to detect 60 metachronous cancers in 2,706 patients.[4,8,10,11,13,15,20,21,23,24] This is a rate of 157 colonoscopies per metachronous cancer detected, which compares favorably to the rate of prevalent cancers detected during screening colonoscopy. Thus, among four screening colonoscopy studies in patients age 50 and old-

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TABLE **4** Additional Recommendations Regarding Postcancer Resection Surveillance Colonoscopy

1. These recommendations assume that colonoscopy is complete to the cecum and that bowel preparation is adequate.
2. There is clear evidence that the quality of examinations is highly variable. A continuous quality improvement process is critical to the effective application of colonoscopy in colorectal cancer prevention.[50]
3. Endoscopists should make clear recommendations to primary care physicians about when the next colonoscopy is indicated.
4. Performance of fecal occult blood test is discouraged in patients undergoing colonoscopic surveillance.
5. Discontinuation of surveillance colonoscopy should be considered in persons with advanced age or comorbidities (with less than 10 years of life expectancy), according to the clinician's judgment.
6. Surveillance guidelines are intended for asymptomatic people. New symptoms may need diagnostic workup.
7. Chromoendoscopy (dye-spraying) and magnification endoscopy are not established as essential to screening or surveillance.
8. Computed tomography colonography (virtual colonoscopy) is not established as a surveillance modality.

TABLE **5** Key Research Questions Regarding Surveillance of the Colorectum after Resection of Colorectal Cancer

1. What clinical, genetic, or biologic markers predict development of metachronous cancers (ie, stratify risk) in colorectal cancer patients without hereditary nonpolyposis colorectal cancer?
2. Are new colorectal cancers in the short-term interval after surgical resection true metachronous cancers or missed synchronous lesions?
3. Do follow-up procedures (flexible sigmoidoscopy, endoscopic ultrasound) after resection of rectal cancer improve any outcomes?
4. Should the treatment of rectal cancer (eg, neoadjuvant chemoradiation, total mesorectal excision) influence whether follow up for local recurrence is justified?
5. Should adjunctive testing (eg, immunochemical fecal occult blood testing) be added to colonoscopy in the surveillance of patients who have undergone resection of colorectal cancer?

er,[54–57] the number of colonoscopies needed to detect one invasive cancer was 135. Excluding reference 55, which was performed in male veterans, (a group expected to have higher prevalence of neoplasia), 156 colonoscopies were performed per invasive cancer detected in the remaining three studies.[54,56,57]

Among studies of post cancer resection surveillance colonoscopy, there were 57 metachronous cancers in the first 2 years after resection of the initial primary, with an incidence rate of 0.7% over this interval. This estimate is consistent with a review of tumor registries in Nebraska, which calculated an annual incidence for metachronous cancers of 0.35% per year.[58] When reported, 69 of 106 (65%) of metachronous cancers were Dukes' Stage A or B,[2,8–10,13,20,23,24] 29 of 52 (56%) were asymptomatic,[2,6,8,10,12,18,20] and 62 of 71 (87%) were operated for cure.[2,6,8,10,12–14,23,24] Taken together, these findings were considered sufficient to warrant a colonoscopy 1 year after resection or after the perioperative clearing colonoscopy for the purpose of identification of apparently metachronous colorectal neoplasms. The recommendation to perform a colonoscopy at 1 year does not diminish the need for high quality in the performance of the perioperative clearing examination(s) for synchronous neoplasms.

Alternatives to Colonoscopy for Surveillance

Colonoscopy is considered the test of choice for detection of metachronous neoplasms in the postcancer resection surveillance colonoscopy setting (Table 4). Double contrast barium enema was less sensitive than colonoscopy for large and small polyp detection after resection of adenomas.[59]

CT colonography has not been evaluated adequately in the surveillance setting, and results for polyp detection are quite mixed.[60–63] Guaiac-based fecal occult blood testing has been generally considered to have very low positive predictive value after clearing colonoscopy. This was confirmed for the first 5 years after colonoscopy in a recent large study.[64] Immunochemical fecal occult blood testing warrants additional evaluation as an adjunct to colonoscopy[65] in this setting. Fecal DNA testing[66] has not been evaluated for postcancer resection surveillance and is not recommended for this indication.

KEY RESEARCH QUESTIONS

There are a number of questions that cannot be fully addressed by currently available evidence. Some of these key research questions are listed in Table 5.

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Appendix B:

Test Your Knowledge and Answer Key

Test Your Knowledge

I. Improving Screening Rates in Practice

1. The most effective tool at a physician's disposal for encouraging patients to be screened is:
   a. A recommendation
   b. An education pamphlet
   c. An educational video
   d. None of the above
   e. All of the above

2. Which of the following have been demonstrated to be effective in raising cancer screening rates?
   a. Postcard reminders
   b. Reminder letters
   c. Prescription reminders
   d. Telephone calls
   e. All of the above

3. Effective chart prompts include:
   a. Problem lists
   b. Screening schedules
   c. Electronic medical record reminders
   d. Chart stickers
   e. All of the above

Choose whether the statements are true or false.	True/False
4. A theory-based communication strategy is more effective than generic education.	_____
5. Provider feedback is an effective way to improve office screening rates.	_____
6. Reassignment of office staff to involve them in the screening process can facilitate improved screening rates.	_____
7. The digital rectal exam is an accepted CRC screening practice.	_____
8. Doctors should do a stool blood test in the office to make sure that at least one CRC screening test is completed.	_____
9. If a stool blood test kit is returned and only one window is positive, the test should be repeated.	_____
10. A positive stool blood test should be repeated if the diet restrictions were not followed.	_____

II. Content of the Current Screening Guidelines

Categorize the risk level of the following patients as average, increased, or high.

11. A 45-year-old woman whose father was diagnosed with a CRC at age 70
    Average Increased High

12. A 30-year-old male whose older brother was diagnosed with an adenomatous polyp at age 59
    Average Increased High

13. A 50-year-old female whose uncle was diagnosed with an adenomatous polyp at age 55
    Average Increased High

14. A 20-year-old woman whose mother died of CRC at age 47
    Average Increased High

Choose the correct answer.

15. At what age should "average-risk" patients begin CRC screening?
    ____ Puberty ____ Age 25 ____ Age 40 ____ Age 50 ____ Age 60

16. At what age should a patient with a family history of colorectal cancer or adenomatous polyps affecting one first-degree relative diagnosed at age 55 begin screening?
    ____ Puberty ___ Age 25 ___ Age 40 _____ Age 50 ____ Age 60

17. What screening modality offers the greatest sensitivity and specificity and should be recommended to those at increased risk?
    ____ Stool blood test ____ Stool blood test/Flexible sigmoidoscopy
    ____ Flexible sigmoidoscopy ____ Colonoscopy ___ Double-contrast barium enema

18. What screening modality might be best to recommend to a patient who is distrustful of physicians or very uncomfortable with invasive procedures?
    ____ Stool blood test ____ Stool blood test/Flexible sigmoidoscopy
    ____ Flexible sigmoidoscopy ____ Colonoscopy ___ Double-contrast barium enema

19. Which of the following screening test(s) are recommended for a 40-year-old patient whose 65-year-old father had colorectal cancer or an adenomatous polyp?
    _____ Stool blood test
    _____ Flexible Sigmoidoscopy
    _____ Stool DNA testing (sDNA)
    _____ Colonoscopy
    _____ Double-contrast barium enema (DCBE)
    _____ All of the above

20. Which of the following screening test(s) are recommended by one or more authoritative groups for patients at risk of hereditary non-polyposis colon cancer (HNPCC) or familial adenomatous polyposis (FAP)? (Choose one.)
    _____ Stool blood test
    _____ Flexible Sigmoidoscopy
    _____ CT colonography (CTC)
    _____ Colonoscopy
    _____ Double-contrast barium enema (DCBE)

Answer Key

I. Improving Practice Screening Rates

1. a. *A recommendation.* The evidence is overwhelming that a doctor's recommendation is the most powerful factor that influences a patient to be screened.
2. e. *All of the above.* There is benefit from patient reminders of many types, as shown by meta-analysis of interventions that effectively increased screening rates for breast cancer.
3. e. *All of the above.* There is benefit from all interventions directed at physicians. This conclusion is based on meta-analyses of the studies on interventions directed at physicians to increase screening rates for breast cancer.

Choose whether the statements are true or false.

4. *True.* Meta-analyses provide strong evidence that theory-based communications are more effective than generic education.
5. *True.* Provider feedback has been shown to be an effective way to improve office screening rates.
6. *True.* Reassignment of office staff to involve them in the screening process can facilitate improved screening rates.
7. *False.* The digital rectal exam is no longer considered to be an accepted method for CRC screening. It is omitted from all consensus guidelines.
8. *False.* This practice is not effective. A single stool blood test in the office does not provide the benefit offered by recommended stool blood test screening practices.
9. *False.* Every positive stool blood test should be followed by a complete diagnostic examination with colonoscopy.
10. *False.* Lack of adherence to the diet is not a reason to depart from the rule that every positive stool blood test should be followed by a complete diagnostic examination with colonoscopy.

II. The Content of the Screening Guidelines

Categorize the risk level of the following patients as average, increased, or high.

11. *Increased.* An individual who has a first-degree relative with CRC is at increased risk. The increased risk is slight due to the older age of the relative. Thus, the American Cancer Society and the US Multi-Society Task Force on Colorectal Cancer recommend management like an average risk patient.
12. *Increased.* All guidelines categorize any individual with a family history of an adenomatous polyp in a first-degree relative that is under age 60 as being at increased risk.
13. *Average.* This woman has an uncle – not a first-degree relative – with a positive history.
14. *Increased.* This patient has a first-degree relative diagnosed with a CRC before age 50. This should also raise concerns about the presence of a hereditary syndrome, and family history should be carefully reviewed.

Choose the correct answer.

15. *Age 50.* This is the age at which "average-risk" patients should begin colorectal cancer screening.
16. *Age 40.* This is the age at which patients at increased risk should begin screening, according to the guidelines of the American Cancer Society and the US Multi-Society Task Force on Colorectal Cancer. These guidelines recommend colonoscopy because the procedure is more sensitive and specific. The US Preventive Services Task Force (USPSTF) recognizes this patient as being at increased risk but does not have a specific recommendation about the age to begin screening or about the best modality. The USPSTF recognizes the colonoscopy as the most sensitive and specific test available.
17. *Colonoscopy.* This method is recognized as the most sensitive and specific screening-test available by all consensus guidelines.
18. *Stool Blood Test.* Stool blood testing is not invasive and can be done by an individual in the privacy of their own home.
19. *Colonoscopy or All of the above.* The patient is at increased risk if a first-degree relative had a CRC or an adenomatous polyp. The risk is slight due to the age (>60) of the first-degree relative. Thus, the American Cancer Society and the US Multi-Society Task Force on Colorectal Cancer would continue to offer all screening options. However, colonoscopy is an apt choice because risk is slightly increased.
20. *Colonoscopy.* Colonoscopy should be utilized to screen those who are at high risk because it is currently the test with the highest level of sensitivity and specificity.

Appendix C:

Barriers to Screening for Colorectal Cancer

Barrier	Clarification and Resolution
Outdated knowledge	• The digital rectal exam is not accepted practice. • A single FOBT in the office is not evidence-based. • A positive FOBT should not be dismissed as a likely false positive test. It should be followed up by a colonoscopy. Introduction, Essential #1, Guidelines.
Inconsistent guidelines	• Physicians often report concerns about inconsistencies in recommended guidelines. • In fact, differences between guidelines are minimal. • Risk stratification must be a priority. Introduction, Essential #2, Guidelines.
Guideline changes	• The digital rectal exam is no longer an accepted screening practice. • As additional evidence becomes available, guideline elements, i.e. age to begin screening, the screening interval, the use of different modalities, also will change. Essential #2, Guidelines.
Screening overestimated	• Physicians frequently estimate higher screening rates than the actual rates. This may dissipate a sense of urgency about screening. The Screening Practices of Primary Care Physicians.
Confusion about goals	• The most common achievement of screening is the removal of an adenomatous polyp. Introduction.
Lack of confidence by doctors	• There is high-quality evidence for the efficacy of screening. • Patient acceptance is better than some physicians may believe. Introduction, Essential #2.
Cost and reimbursement	• Cost of FOBT is low and colonoscopy cost is declining. • Consult health departments where the uninsured cannot access complete diagnostic examinations. • Discuss the barrier of copays and deductibles. Introduction.
Inadequate resources and reinforcement systems	• Nationwide, there are sufficient resources to screen the entire eligible population within one year with FOBT, plus colonoscopy for all positives. (See reference #38.) • Communication strategies can raise efficiency. • Office reminder and reinforcement systems are discussed in the section "Essential #3." Introduction, Essential #4, The Screening Practices of Primary Care Physicians.

Barriers to Screening for Colorectal Cancer

While there are a number of barriers to improved screening rates, the tools in this guide will help transcend the barriers. Of the barriers in this section, the majority may be overcome through use of the information and strategies that are offered in this publication. The sections of the guide where each barrier is addressed are identified in the table.

Outdated Knowledge

This section will discuss the following practices, which are not evidence-based approaches to screening:

- **The digital rectal exam**
- **A single stool blood test in the office**
- **The "False-Positive" stool blood test**

The digital rectal exam. The digital rectal exam (DRE) is no longer recommended for CRC screening. It is not a recommended strategy in any of the three major guidelines: from the American Cancer Society, the US Multi-Society Task Force on Colorectal Cancer, or the US Preventive Services Task Force (USPSTF). Only 10 percent of CRCs arise within reach of the examining finger.[165] A study reported in the *Annals of Internal Medicine* demonstrated that the sensitivity of the digital gFOBT is 4.9 percent for advanced neoplasia, compared to 23.9 percent for the six-sample home gFOBT.[166] The digital rectal exam is not an effective screening exam for colorectal cancer.

More than a decade ago, the DRE was recommended as part of the screening exam for CRC for average-risk individuals by the American Cancer Society, the National Cancer Institute, and national professional societies, and the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, and the American Society of Colon and Rectal Surgeons.[167] **This approach has been abandoned.** Recent evidence demonstrates that this is ineffective for colorectal cancer screening. It should be noted, however, that since the prostate is within the range of the examining finger, the DRE remains an accepted strategy for prostate cancer.

A single stool blood test sample taken in the office. A single stool blood test that is performed in the office is not sound practice.†††††† In one study, cited by the USPSTF, the first test card would have missed 42 percent of cancers that were detected by screening.[168] And in a more recent study of more than 2,600 patients who underwent colonoscopy, 95 percent of cancers and significant adenomas went undetected by the single sample stool blood test.[169] No guideline or group recommends a "single stool blood test in the office" as part of the screening regimen. In the past, it was common practice to do a stool blood test in the office during the complete physical as an opportunity to complete one stool blood test. The studies cited above put this view to rest. Some physicians home-based gFOBT. This belief is incorrect.

†††††† The evidence for the effectiveness of FOBT as a screening test is based on the completion of three FOBT cards over three days, and on repeat of this process on an annual basis. A single FOBT in the office is not sensitive enough to satisfy the requirements of a screening test.

The "False- Positive" stool blood test. One positive stool blood test window is always an indication for a colonoscopy. There is no justification for repeating a positive stool blood test with another stool blood test. The suspicion that the positive is false because the patient failed to adhere to dietary instructions or medication restrictions is not a relevant concern. The effectiveness of the stool blood test as a screening strategy rests on complete examination of the large bowel following the finding of any positive stool blood test. In addition, the complete diagnostic examination should be done by colonoscopy – not double-contrast barium enema (DCBE) – because it is more sensitive and more specific than DCBE. In one study cited earlier, only 50 percent of patients with a positive stool blood test went on to receive a complete examination of the colon.

Inconsistent Guidelines Despite Unanimity on Principle

Minor inconsistencies in the guidelines have created confusion that must be eliminated. All the guidelines are consistent about the recommendation to screen. All agree there is strong evidence in favor of screening for colorectal cancer. The guidelines differ only in emphasis and in limited ways that create the impression of inconsistency. In a recent survey of physicians, only 37 percent thought the guidelines were clear. Compared to the other guidelines, the USPSTF guidelines seem to promote a narrower array of screening modalities, emphasize a more limited definition of risk, and suggest different ages for initiation of screening. In truth, these are minor variations in emphasis and there is unanimity about the importance of CRC screening. The areas of apparent inconsistency are:

- **Screening options**
- **Risk stratification**
- **Age**

Screening Options. The 2008 American Cancer Society/US Multi-Society Task Force on Colorectal Cancer/American College of Radiology update of the guidelines endorses the value of a variety of screening options and presents the evidence regarding each option. The 2002 USPSTF guideline distinguishes between the options and expresses less enthusiasm for four of them. In the summary statement, the USPSTF states that the use of stool blood test is supported by "good" evidence; FS or stool blood test/FS are supported by "fair" evidence; colonoscopy is supported by no "direct evidence"; and, DCBE is described as "less sensitive" than colonoscopy. However, the USPSTF makes it clear up front that it "strongly recommends that clinicians screen men and women 50 years of age or older for colorectal cancer."[171] The USPSTF also states that "colonoscopy is the most sensitive and specific test for detecting cancer and large polyps."

Risk Stratification. The guidelines differ in their emphasis on risk and the choice of screening modality in response to risk. The American Cancer Society and the US Multi-Society Task Force on Colorectal Cancer recommend risk stratification as the initial step in determining the appropriate screen for each individual. They recommend colonoscopy for people at increased risk. A family history of colorectal cancer or adenomatous polyp in a first-degree relative increases the lifetime risk of CRC by two to three times, bringing it to 12 to 18 percent. If a first-degree relative presents with one of these at a young age (under 60), the lifetime risk is even greater. Lifetime risk is also increased – but less so – if these factors are present in a second-degree relative, or even a third-degree relative.

The USPSTF focuses its recommendations on people at average risk. This focus is apparent in the way the recommendations are presented and summarized. Though the epidemiology section lists the risk factors (genetic syndromes, family history of CRC, long-standing ulcerative colitis, personal history of adenomatous polyps or family history of adenomatous polyps in a relative under age 60) and identifies the prevalence of adenomatous polyps as 20 to 25 percent by age 50, and 50 percent by age 75 to 80,[172 173] the USPSTF summary has no special recommendation for management of the common risk factors. The USPSTF concedes that colonoscopy "may be appropriate" with "very high-risk patients,"[174] with the specific groups being those with familial syndromes (FAP, HNPCC) or a personal history of long-standing ulcerative colitis, not the other more common risk experiences presented in the epidemiology section.

Age. The last updates of the American Cancer Society and the US Multi-Society Task Force on Colorectal Cancer guidelines for increased and high-risk individuals recommend that screening begin 10 years before the age of the youngest relative who presented with either CRC or adenomatous polyps or at age 40, whichever comes first. The USPSTF states that, for people at higher risk (i.e. where there is a first-degree relative diagnosed with CRC before age 60), "initiating screening at an earlier age is reasonable."

Guideline Changes

Some physicians may not be aware that the guidelines have all been updated in response to new evidence, most recently in 2002 (USPSTF) and 2008 (ACS/USMSTF/ACR). As evidence has accumulated, guidelines have changed. The newest guidelines superceded guidelines articulated in 1996, 1997, and 2000. Earlier guidelines date back further and may still be fixed in the minds of some practitioners. The changes are quite significant. In 1989, the US Preventive Services Task Force judged there was insufficient evidence to recommend for or against gFOBT or FS screening.[175] By 2002, the USPSTF found evidence that several screening methods were effective in reducing mortality. Specific areas of change include:

- **The digital rectal exam**
- **Age**
- **Diagnostic workup**

The Digital Rectal Exam. The digital rectal exam is no longer considered a useful screening exam for colorectal cancer. In 1989, a digital rectal exam was considered standard practice in the health maintenance exam to look for CRC and prostate cancer.[176 177] The digital rectal exam continued to be recommended for screening for both cancers into the mid-1990s. Today, it is recommended as a screening exam for prostate cancer only, not colorectal cancer.

Age. Age 50 is currently recommended as the advent of screening for individuals at average risk. Earlier is better for individuals at increased risk. In the past, the age to begin screening those at average risk was earlier.[178] The American Cancer Society formerly recommended that screening begin at age 40. The age for screening people at increased risk has also varied. In 1979, the Canadian Task Force on the Periodic Health Examination recommended starting at age 45 with an annual stool blood test for those at increased risk. Current recommendations of the American Cancer Society and the US Multi-Society Task Force on Colorectal Cancer are to begin screening 10 years before the youngest relative affected or at age 40.

Diagnostic WorkUp. The recommended workup after a positive stool blood test has changed somewhat since 1997. The American Cancer Society and the US Multi-Society Task Force on Colorectal Cancer previously recommended a colonoscopy or, as an alternative, DCBE plus a flexible sigmoidoscopy. The American Cancer Society and the US Multi-Society Task Force on Colorectal Cancer now recommend a colonoscopy only for this workup because all the evidence for the effectiveness of stool blood testing in reducing mortality is based on diagnostic evaluation with colonoscopy.

Overestimation of Current Screening Rates

Overestimation of screening rates may lull physicians into making less effort than needed to assure that every eligible patient leaves the practice with a recommendation for screening. The fact is that CRC screening rates remain low across the country.‡‡‡‡‡‡ Physicians frequently estimate higher screening rates than the actual rates. This may dissipate a sense of urgency about screening. Further, news coverage of emerging technologies may also undercut current efforts to increase screening. Some patients and providers may decide to wait until "better" screening methods are available – not realizing how long that wait will be.

Confusion about Priorities and Goals[179]

Even a screening program that identifies relatively few cancers can be highly successful by preventing colorectal cancer. There are two equally important goals of screening. One is to prevent CRC, and thereby reduce the incidence of new cancers. The other is to reduce mortality from existing colorectal cancers. Cancers are prevented when adenomatous polyps are removed before they become cancerous. The removal of early CRCs before they become later-stage cancers further improves the prognosis. The first of the two goals is the more common achievement. Ten to 20 percent of endoscopies find adenomatous polyps. Only 1 percent of endoscopies find a cancer. Due to the tremendous potential for cancer prevention through polyp detection and removal, the 2008 ACS/USMSTF/ACR screening guidelines emphatically state that *colon cancer prevention* should be the primary goal of colorectal cancer screening. These recommendations go on to state that patients should be encouraged to be screened with testing methods that are more likely to detect both early cancer and precancerous polyps (i.e. flexible sigmoidoscopy, colonoscopy, double-contrast barium enema and CT colonography) if resources are available and patients are willing to undergo an invasive test.

Lack of Confidence in Efficacy and Acceptability

Despite strong new evidence that supports the efficacy of screening, some physicians may lack confidence in the efficacy of CRC screening tests. Stool blood test is the most popular recommendation, but only 24 to 35 percent of primary care physicians believe that stool blood tests are "very effective" in reducing mortality, despite evidence from randomized controlled studies.[180 181] Only 43 to 59 percent believe that FS is "very effective" in reducing mortality, despite the fact that new evidence showed that stool blood test plus FS (followed by colonoscopy for the positives) achieved a detection rate of 75.8 percent.§§§§§§ [182]

‡‡‡‡‡‡ CRC screening rates for every state are available in the Behavioral Risk Surveillance System at www.cdc.gov.
§§§§§§ Detection was of adenoma of 10 mm or more, or of adenoma that was 25 percent villous, showed high-grade dysplasia, or was classified as invasive cancer.

Some physicians may believe that a flexible sigmoidoscopy or a colonoscopy is a highly distasteful choice for their patients. Though there is little evidence for this, at least one statewide survey has documented that less than 5 percent of those surveyed found the nature of these tests an inhibiting factor.[183]

Cost and Reimbursement

There are routes available to overcome some cost barriers. While some private insurers may not pay for all screening tests, most insurers pay for some type of screening. Most will support a diagnostic colonoscopy if the result of a stool blood test is positive. Stool blood tests are inexpensive tests and can be performed at home. They may be accessed at pharmacies in many areas of the country. In a study of physician attitudes in Wisconsin, cost was the most common explanation for not recommending colonoscopy.[184] Cost may be less of an issue now than it was previously. In 2004, due to the predominance on the system of Medicare rates, colonoscopy was reimbursed at $300 to $400 in many locations, with a similar amount for the facility fee, and modest additional costs for anesthesia, bringing the total cost to $800 to $900. These payment levels applied if the procedure was performed in an ambulatory endoscopy or surgery center. For a procedure performed in the hospital, the charge was in the $1,200 to $1,500 range. However, screening colonoscopy is performed every 10 years, making the hospital-based costs similar to the cost of annual mammography when calculated as an annual cost. Stool DNA cost estimates range from $300 to $400 per episode of testing. Medicare and most private insurance plans do not currently pay for stool DNA testing or for CT colonography when used in a screening capacity, though as of this writing, Medicare is evaluating the evidence around CT colonography for colorectal cancer screening to determine if it should be covered. Medicare does pay for screening colonoscopy and most other screening options. And although screening CTC is not yet reimbursable through the program, 47 states now offer Medicare reimbursement for diagnostic CTC for certain clinical indications (typically limited to patients who have had an incomplete optical colonoscopy).*******

An entry physical that includes CRC screening is a part of the Medicare routine, as of 2005. Some states have regulations that shape insurance coverage. In 26 states and the District of Columbia, insurance plans are required to pay for all CRC screening options, with the exception of the recently added stool DNA testing and CT Colonography. The Health Plan Employer Data and Information Set (HEDIS) reporting requirements (the employers' required data set for health plans) now include CRC screening rates. These are reported to the public as of 2006. This will influence insurers to include CRC in standard policies and pay for more options. However, even where reimbursement is available, deductibles and copays may be a barrier. It has been documented based on data from the National Health Interview Survey, that among people with either Medicare or private insurance coverage, those with lower incomes get screened at a significantly lower rate than those with higher incomes.[185]

Also of great concern are the 45 million individuals who lack health insurance coverage.

******* Medicare issued a new policy in 2001. It began paying for screening CS every 10 years. No longer are symptoms of CRC required in order for Medicare to reimburse for screening colonoscopy.

While all uninsured individuals are at risk and much less likely to get screened, uninsured people in the increased risk groups are more likely to suffer the consequences of lack of insurance. For individuals at increased risk, the lack of insurance can be a highly detrimental barrier. Some areas of the country have programs available that provide access to colorectal cancer screening and colonoscopy if it is indicated.

Inadequate Medical Resources and Reinforcement Systems

Inadequate local medical resources may appear to present a barrier. If screening rates are increased, knowledge of local resources is key. While primary care physicians recommend several screening choices to their patients, it has become difficult to obtain flexible sigmoidoscopy in many areas of the country.[186] [187] The use of this test has declined.[188] In areas where reimbursement has declined steeply, sigmoidoscopy is available only on a limited basis.

Staffing needs have grown due to the more complex reimbursement milieu of managed care, and there is concern that patient education wastes time and detracts from activities that better support the bottom line.[190] Efficient communication and reminder systems are needed if office practices are to succeed in raising screening rates.

Offices appear to make limited use of reminder systems despite the evidence for them. A Wisconsin survey revealed that only 5 percent of primary care physicians had a computer reminder system; 37 percent had a paper reminder system; and 58 percent had no reminder system at all.[191] The lengthy interval between screening tests (FS every five years or CS every 10 years) makes it difficult to maintain follow up and makes reminder systems even more important, unlike the annual mammogram and stool blood test, which are easy to remember. In the absence of reminder systems, it is difficult to identify patients who are due for screening or to contact them. Since referral and scheduling processes are often cumbersome, time-consuming, and discouraging, follow up is essential. Tracking patients through the system, or waiting for feedback from consultants to confirm follow up and follow-through, may be a challenge. More attention is needed to the system by which results are communicated from consultants to primary care doctors.

Appendix D: Tools

I. Phone Scripts, Reminder Letters, Postcards
II. Preventive Services Schedules
III. Audit and Tracking Sheets
IV. Brochures, Pamphlets, Posters

I. Phone Scripts, Reminder Letters, Postcards

gFOBT/FIT Follow-up Phone Script for Average-Risk Individuals

Introduction:

Good morning/afternoon. May I speak with _____?
(Note: Due to HIPAA regulations, the conversation should not proceed unless speaking directly with the patient.)

My name is _____ and I am calling from _____ .

You recently received a stool test for colon cancer screening.

Did you have any questions about the test?

We are calling everyone who received one of these to see if there is any way we can help you complete the test.

1. "Have you had the chance to complete and mail your kit?"

If the answer is YES, get the approximate date to ensure that the test will be valid, and get the approximate date of receipt. Thank the participant and let him or her know that you will mail them the results.

If the answer is NO, ask the following question.

Mr./Ms._____, is there any reason why you have not completed your kit? (Document reason; possible reasons are listed below.)

- ☐ Diet and drug restrictions
- ☐ Test is difficult and disgusting.
- ☐ Haven't had the time
- ☐ Changed my mind
- ☐ Received other colorectal cancer testing
- ☐ Believe it is not effective way of screening
- ☐ Health insurance/doctor

Source: Maryland State Cancer Program, adapted from materials of the Montgomery County Cancer Crusade, 2001.

2. **Emphasize the benefits of screening and program services.**

   "Colorectal cancer can affect anyone – men and women alike – and your risk increases with age. Colorectal cancer is highly preventable, treatable, and often curable. There are several screening tests for colorectal cancer. These tests not only detect colorectal cancer early, but also can prevent colorectal cancer.

   Beginning at age 50, men and women should be screened regularly for colorectal cancer. If you have a personal or family history of colorectal cancer or colorectal polyps, or personal history of another cancer or inflammatory bowel disease, you should begin screening earlier.

3. **If patient indicates that he or she prefers a colonoscopy, ask "Do you have health insurance?"**

   If he or she is insured, suggest a visit to an endoscopist (gastroenterologist or general surgeon) for a colonoscopy. If he or she does not know a gastroenterologist, give physician referral phone number and appropriate form.

   If he or she is uninsured, encourage him or her to follow through with a stool blood test.

   Mr./Ms._____ Thank you for your time today.

   Do you have any questions? If you need further assistance completing your kit or have any questions, please give us a call at_____ .

Note: Please document and track these conversations.

Follow-up Phone Script for Individuals at Increased Risk

Introduction:

Good morning/afternoon. May I speak with _____ DOB: _____
(Full Name)

(Note: Due to HIPAA regulations, the conversation should not proceed unless speaking directly with the patient.)

My name is _____ and I am calling from _____ .

You recently received a referral for a colonoscopy screening test for colon cancer.

Did you have any questions about the test?

We are calling to see if there is any way we can help you get screening for colorectal cancer.

1. **"I see that on the form you filled out, you checked off." (Confirm their response.)**

   ☐ Family history of colorectal cancer or polyps – specify: _____
   ☐ Personal history of colorectal cancer or polyps – specify: _____
   or *inflammatory bowel disease – specify: _____

2. **"Can you tell me more about your history (family history) or symptoms?"**

   Assess the history or symptoms for significance. (Significant personal or family history is an adenomatous polyp or colorectal cancer in one first-order relative under age 60 or more than one first- or second-degree relative over age 60, or a personal history of inflammatory bowel disease such as Crohn's disease or ulcerative colitis* for more than eight years.)

3. **"Because of your history/family history/symptoms, we recommend that you have a colonoscopy for proper screening."**

4. **If the person needs more motivation, emphasize the benefits of screening.**

   "Colorectal cancer can affect anyone – men and women alike – and your risk increases with age. Colorectal cancer is highly preventable, treatable, and often curable. Most colorectal cancers cause no symptoms in the early stages, which is why screening is so important. There are several screening tests for colorectal cancer. These tests not only detect colorectal cancer early but can also prevent colorectal cancer. Beginning at age 50, men and women should be screened regularly for colorectal cancer. If you have a personal or family history of colorectal cancer or colorectal polyps, or a personal history of an inflammatory bowel disease, you should begin screening earlier."

   * Inflammatory bowel disease – ulcerative colitis, Crohn's disease

Source: Maryland State Cancer Program, Montgomery County Cancer Crusade, 2001.

5. **"Have you heard about the colonoscopy (or other procedures)?" Discuss as appropriate.**

   If further assessment indicates that the individual is at increased risk or has significant symptoms, continue to encourage a colonoscopy.

6. **"Do you have health insurance? Do you have a gastroenterologist or surgeon who does colonoscopy?"**

   Respond as appropriate with suggestions and problem solving. **If the person is uninsured,** explore alternative options that are available. The office should determine in advance what these options might be.

   Mr./Ms._____ Thank you for your time today.

   Do you have any questions? If you need further assistance or have any questions, please give us a call at_____ .

Letter to Patient at Average Risk

MAIN STREET MEDICAL

Date

Name
Street
City

Dear (Name):

Our office has made a commitment to promote the health of its members, and to provide education regarding preventive health measures that you can take to maintain a healthy lifestyle. Our records indicate that you are either overdue for colorectal cancer screening tests, or that you have never had a colorectal cancer screening test.

I am writing to ask you to call our office today to schedule a colorectal cancer screening appointment. By getting colorectal cancer screening tests regularly, colorectal cancer can be found and treated early when the chances for cure are best. Many of these tests can also help prevent the development of colorectal cancer.

The American Cancer Society and a number of other major medical organizations recommend that average-risk individuals choose one of the following options for colorectal cancer screening. Screening should begin at age 50.

Tests That Find Polyps and Cancer

- Flexible sigmoidoscopy every 5 years*, or
- Colonoscopy every 10 years, or
- Double-contrast barium enema every 5 years*, or
- CT colonography (virtual colonoscopy) every 5 years*

Tests That Primarily Find Cancer

- Yearly fecal occult blood test (gFOBT)*,**, or
- Yearly fecal immunochemical test (FIT)*,**, or
- Stool DNA test (sDNA), interval uncertain*

* If the test is positive, a colonoscopy should be done.
** The multiple stool take-home test should be used. One test done by the doctor in the office is not adequate for testing. A colonoscopy should be done if the test is positive.

The tests that are designed to find both early cancer and polyps are preferred if these tests are available to you and you are willing to have one of these more invasive tests. Talk to your doctor about which test is best for you.

We have also included for your reference an informational pamphlet on colorectal cancer. Should you have any questions about this pamphlet or colorectal cancer screening tests, please contact us. Thank you for taking time to take care of your health.

Sincerely,

Enclosure: *Colorectal Cancer Screening Brochure*

Reminder Letter to Patient at Average Risk

MAIN STREET MEDICAL

Date

Name
Street
City

Dear (Name):

Colorectal cancer is the second leading cause of cancer death among men and women in the United States. The good news is that this disease can be prevented. Screening tests are vital to preventing colorectal cancer because they can detect precancerous polyps that can be removed easily with routine procedures. Lifestyle changes, such as improving diet and increasing physical activity, can also reduce the risk of cancer.

Like many people, you are at risk for colorectal cancer. I am writing to remind you to call your primary care physician today to schedule a colorectal cancer screening appointment. By getting colorectal cancer screening tests regularly, colorectal cancer can be found and treated early when the chances for cure are best.

Please read the enclosed brochure to learn about colorectal cancer screening. If you'd like to know more about colon cancer and the testing process, I would be happy to talk with you about it further. You can also call the American Cancer Society at 1-800-ACS-2345 or visit www.cancer.org. Whatever your next step, I hope you'll schedule your next screening test soon. It just might save your life.

Sincerely,

Enclosure: *Colorectal Cancer Screening brochure*

Reminder Fold-Over Postcard

MAIN STREET MEDICAL

Date

Dear (Name):

Colon cancer is the second leading cause of cancer-related deaths in the United States, and men and women are equally at risk. The good news is that colon cancer can be prevented or detected early and death from colon cancer can be prevented if screening is done on a regular basis.

Our records indicate that it is time for your annual physical and cancer screening. Please call your primary care physician, at XXX-XXX-XXXX so that you can schedule an appointment at your earliest convenience.

Sincerely,

Letter to Patient at Increased or High Risk

Main Street Medical

Date

Name
Street
City

Dear (Name):

According to our records, you indicated that either you or a family member who is under age 60 has a history of colorectal polyps or cancer. This medical history places you at increased risk for colorectal cancer. Because of this, it is advisable that you have a colonoscopy now.

Colonoscopy is the only method of screening recommended for individuals like you who are known to be at increased risk for colorectal cancer. Even if you had a negative stool blood test or other screening test for colorectal cancer, you still need a colonoscopy.

A colonoscopy is a procedure that must be done by a gastroenterologist or a surgeon at an endoscopy center or hospital. This test will allow a doctor to look inside the entire colon (large intestine) to check for a polyp or cancer.

If you do not have health insurance, please do not let this keep you from getting a colonoscopy. We can assist you with scheduling a colonoscopy or finding a doctor who will see you. Please call _____to set up an appointment, if you have questions.

If you have private health insurance (Medicare or Medicaid), our office will refer you for a colonoscopy. To obtain the referral, call or take this letter with you to your next doctor's appointment.

Thank you for taking care of your health and following through on this important test.

Sincerely,

Medical Director

Result Letter: Patient Who Has a Positive Screening Result

Note that this letter is for stool blood test, but a similar letter should be sent for patients with positive stool DNA, CT colonography, double-contrast barium enema, or flexible sigmoidoscopy.

MAIN STREET MEDICAL

Date

Name
Street
City

Dear _____,

We wanted to congratulate you on successfully completing the stool blood test. The results of your test for colon and rectal cancer screening showed that you may have blood in your stool and that further testing is needed.

You now need a colonoscopy to look for a possible source of the bleeding and to determine if a polyp or cancer is present. Usually there is no serious problem. If a precancerous growth is found, it can be removed to prevent cancer. However, cancer is one of the potential causes for your bleeding and we want to be very careful to rule out this possibility. A colonoscopy is a procedure that must be done by a doctor at an endoscopy center or a hospital. This test will require that you have anesthesia and will allow a doctor to look inside your entire large intestine to check for a growth or a polyp or cancer. The doctor will explain the colonoscopy results to you after the test.

We can assist you with scheduling a colonoscopy. Please call or visit our office at _____ to obtain a referral or set up an appointment. Also, please take this letter with you to your next doctor's appointment.

Thank you for following up on your health care needs. I am enclosing a brochure that describes colonoscopy. We have a videotape available if you would like to view it.

Sincerely,

Medical Director

Enclosure

II. Preventive Services Schedules*

* To remain up to date, see www.preventiveservices.ahrq.gov.

Adult Female Age 50 to 65 Preventive Care Flow Sheet

PATIENT NAME_____
DOB_____/_____/_____

Put Prevention Into Practice

DATE																				
HEALTH GUIDELINES		**50**	**51**	**52**	**53**	**54**	**55**	**56**	**57**	**58**	**59**	**60**	**61**	**62**	**63**	**64**	**65**	**66**	**67**	**68**
Abuse																				
Advance directives																				
Breast self-exam																				
Calcium																				
Dental health																				
Drugs/alcohol																				
Estrogen																				
HIV/AIDS																				
Injuries																				
Mental health/depression																				
Nutrition																				
Occupational health																				
Physical activity																				
Sexual behavior																				
Tobacco																				
UV exposure																				
Violence & guns																				
✔ = Discussed w/ patient																				

EXAMINATION & TESTS		**50**	**51**	**52**	**53**	**54**	**55**	**56**	**57**	**58**	**59**	**60**	**61**	**62**	**63**	**64**	**65**	**66**	**67**	**68**
Height, weight	Each visit																			
Blood pressure	Each visit																			
Skin, oral, thyroid exam																				
Pelvic/PAP																				
STD screening	Sexually active																			
Rectal exam																				
Stool test (home)	Annual ≥50y																			
Breast exam	Annual																			
Mammogram	Annual																			
Flex, Sig, CTC, DCBE	≥50y q5y																			
Colonscopy	≤50y q 10 or high risk																			
Vision, glaucoma screen																				
Cholesterol/lipid profile	q5y																			
Glucose, fasting	q5y																			
Urinalysis	q5y																			
TB skin test	High risk: annual																			
Other																				

IMMUNIZATIONS*		**50**	**51**	**52**	**53**	**54**	**55**	**56**	**57**	**58**	**59**	**60**	**61**	**62**	**63**	**64**	**65**	**66**	**67**	**68**
Td	q10y																			
Influenza	Annual																			
Pneumovax	>65y or high risk																			
Hepatitis B	High risk																			

O = Ordered, N = Normal, A = Abnormal Result, R = Refused, E = Done Elsewhere

Source: Adopted from Moser SE, Goering TL. Implementing preventive care flow sheets. *Fam Pract Manage.* February 2001:51-53.
Flow sheet developed by Wesley Medical Center, Wichita, Kan.; adapted from Put Prevention Into Practice, Office of Disease Prevention and Health Promotion, Public Health Service.

* For current recommendations of immunization practices, go to www.cdc.gov

Adult Female Over 65 Preventive Care Flow Sheet

PATIENT NAME_____
DOB_____/_____/_____

Put Prevention Into Practice

DATE																				
HEALTH GUIDELINES		**AGE**																		
Abuse																				
Advance directives																				
Breast self-exam																				
Calcium																				
Dental health																				
Drugs/alcohol																				
Estrogen																				
HIV/AIDS																				
Injuries																				
Mental health/depression																				
Nutrition																				
Occupational health																				
Physical activity																				
Sexual behavior																				
Tobacco																				
UV exposure																				
Violence & guns																				
✔ = Discussed w/ patient																				

EXAMINATION & TESTS																				
Height, weight	Each visit																			
Blood pressure	Each visit																			
Skin, oral, thyroid exam																				
Pelvic/PAP																				
STD screening	Sexually active																			
Rectal exam																				
Stool test (home)	Annual ≥50y																			
Breast exam	Annual																			
Mammogram	Annual																			
Flex, Sig, CTC, DCBE	≥50y q5y																			
Colonscopy	≤50y q 10 or high risk																			
Vision, glaucoma screen																				
Cholesterol/lipid profile	q5y																			
Glucose, fasting	q5y																			
Urinalysis	q5y																			
TB skin test	High risk: annual																			
Other																				

IMMUNIZATIONS*																				
Td	q10y																			
Influenza	Annual																			
Pneumovax	>65y or high risk																			
Hepatitis B	High risk																			

O = Ordered, N = Normal, A = Abnormal Result, R = Refused, E = Done Elsewhere

Source: Adopted from Moser SE, Goering TL. Implementing preventive care flow sheets. *Fam Pract Manage.* February 2001:51-53.
Flow sheet developed by Wesley Medical Center, Wichita, Kan.; adapted from Put Prevention Into Practice, Office of Disease Prevention and Health Promotion, Public Health Service.

* For current recommendations of immunization practices, go to www.cdc.gov

Adult Male Age 50 to 65 Preventive Care Flow Sheet

PATIENT NAME_____
DOB_____/_____/_____

Put Prevention Into Practice

DATE																				
HEALTH GUIDELINES		**50**	**51**	**52**	**53**	**54**	**55**	**56**	**57**	**58**	**59**	**60**	**61**	**62**	**63**	**64**	**65**	**66**	**67**	**68**
Abuse																				
Advance directives																				
Aspirin																				
Dental health																				
Drugs/alcohol																				
HIV/AIDS																				
Injuries																				
Mental health/depression																				
Nutrition																				
Occupational health																				
Physical activity																				
Sexual behavior																				
Testicular self-exam																				
Tobacco																				
UV exposure																				
Violence & guns																				
✔ = Discussed w/ patient																				

EXAMINATION & TESTS		**50**	**51**	**52**	**53**	**54**	**55**	**56**	**57**	**58**	**59**	**60**	**61**	**62**	**63**	**64**	**65**	**66**	**67**	**68**
Height, weight	Each visit																			
Blood pressure	Each visit																			
Skin, oral, thyroid exam																				
Rectal prostate exam	annual ≥40 y																			
Stool test (home)	Annual ≥50y																			
Testicular exam																				
STD screening	Sexually active																			
Flex, Sig, CTC, DCBE	≥50y q5y																			
Colonscopy	≤50y q 10 or high risk																			
Vision, glaucoma screen																				
Cholesterol/lipid profile	q5yr																			
Glucose, fasting	q5y																			
TB skin test	High risk: annual																			
PSA	FH-: qy ≥ 50, FH+: qy ≥ 40																			

IMMUNIZATIONS*		**50**	**51**	**52**	**53**	**54**	**55**	**56**	**57**	**58**	**59**	**60**	**61**	**62**	**63**	**64**	**65**	**66**	**67**	**68**
Td	q10y																			
Influenza	Annual																			
Pneumovax	>65 or high risk																			
Hepatitis B	High risk																			

O = Ordered, N = Normal, A = Abnormal Result, R = Refused, E = Done Elsewhere

Source: Adopted from Moser SE, Goering TL. Implementing preventive care flow sheets. *Fam Pract Manage.* February 2001:51-53.
Flow sheet developed by Wesley Medical Center, Wichita, Kan.; adapted from Put Prevention Into Practice, Office of Disease Prevention and Health Promotion, Public Health Service.

* For current recommendations of immunization practices, go to www.cdc.gov

Adult Male Over 65 Preventive Care Flow Sheet

PATIENT NAME_____
DOB_____/_____/_____

Put Prevention Into Practice

DATE																				
HEALTH GUIDELINES		**AGE**																		
Abuse																				
Advance directives																				
Aspirin																				
Dental health																				
Drugs/alcohol																				
HIV/AIDS																				
Injuries																				
Mental health/depression																				
Nutrition																				
Occupational health																				
Physical activity																				
Sexual behavior																				
Testicular self-exam																				
Tobacco																				
UV exposure																				
Violence & guns																				
✔ = Discussed w/ patient																				

EXAMINATION & TESTS																				
Height, weight	Each visit																			
Blood pressure	Each visit																			
Skin, oral, thyroid exam																				
Rectal prostate exam	Annual																			
Stool test (home)	Annual ≥50																			
Testicular exam																				
STD screening	Sexually active																			
Flex, Sig, CTC, DCBE	≥50y q5y																			
Colonscopy	≤50y q 10 or high risk																			
Vision, glaucoma screen																				
Cholesterol/lipid profile	q5yr																			
Glucose, fasting	q5y																			
TB skin test	High risk: annual																			
PSA	FH-: qy ≥ 50, FH+: qy ≥ 40																			

IMMUNIZATIONS*																				
Td	q10y																			
Influenza	Annual for > 65y																			
Pneumovax	>65 or high risk																			
Hepatitis B	High risk																			

O = Ordered, N = Normal, A = Abnormal Result, R = Refused, E = Done Elsewhere

Source: Adopted from Moser SE, Goering TL. Implementing preventive care flow sheets. *Fam Pract Manage.* February 2001:51-53.
Flow sheet developed by Wesley Medical Center, Wichita, Kan.; adapted from Put Prevention Into Practice, Office of Disease Prevention and Health Promotion, Public Health Service.

* For current recommendations of immunization practices, go to www.cdc.gov

III. Audit and Tracking Sheets

Chart Audit SAMPLE Template[b]

					FOBT/FIT			Flex Sig/CTC/DCBE			Colonoscopy			
Name ID	Date	Gender Race Ethnicity	Screen Choice FOBT/FIT, FS, CS, CTC, DCBE	FOBT/FIT Return Test Completed Y/N	Result	Result Date	Flex Sig CTC/DCBE Test Completed Y/N	Result	Result Date	CS Completed Y/N	Result	Result Date	Diagnosis

Source: Adapted from materials developed by the Maryland Department of Health and Mental Hygiene Cancer Prevention Education Screening and Treatment Program.

Colorectal Cancer Screening – SAMPLE Tracking Template*

		Date
1.	a. At-home FOBT/FIT kit given	_____
	b. FOBT/FIT test completed	_____
	c. Results received	_____
	d. If no completion or results, reminder card/letter sent	_____
	e. Patient notified of finding	_____
	f. Referred for CS if positive	_____
	g. Placed in tickler file if negative for next year	_____
2.	a. Referred for FS	_____
	b. FS scheduled	_____
	c. FS test completed	_____
	d. FS results received	_____
	e. If no completion or results, FS reminder card/letter sent	_____
	f. FS patient notified of finding	_____
	g. FS placed in tickler file if negative	_____
	h. Scheduled for CS if positive	_____
3.	a. Referred for CS	_____
	b. CS scheduled	_____
	c. CS test completed	_____
	d. CS results received	_____
	e. If no completion or results, CS reminder card/letter sent	_____
	f. CS patient notified of finding	_____
	g. CS placed in tickler file if negative	_____

Colorectal Cancer Screening – SAMPLE Tracking Template*
(continued)

		Date
4.	a. Referred for CTC	_____
	b. CTC scheduled	_____
	c. CTC test completed	_____
	d. CTC results received	_____
	e. If no completion or results, CTC reminder card/letter sent	_____
	f. CTC patient notified of finding	_____
	g. CTC placed in tickler file if negative	_____
	h. Scheduled for CS if positive	_____

* Adapted from materials developed by the Maryland Department of Health and Mental Hygiene Cancer Prevention Education Screening and Treatment Program.

IV. Brochures, Pamphlets, Posters

Resources

From the Centers for Disease Control and Prevention
http://www.cdc.gov/cancer/colorectal/

Fact sheets:
- Questions to Ask Your Doctor
- Screening Tests
- Screening Guidelines
- Insurance and Medicare

Brochures:
- Colorectal Cancer Screening Saves Lives
- Screen for Life Facts for People with Medicare Colorectal
- Cancer Screening: A Circle of Health for Alaskans
- Screen for Life Health Professionals Facts on Screening

From the National Cancer Institute
http://www.cancer.gov/cancertopics/types/colon-and-rectal

Booklet:
- What you need to know about cancer of the colon and rectum (also available in Spanish)

From the Foundation of Digestive Health and Nutrition
http://www.fdhn.org/wmspage.cfm?parm1=210

Fact sheet:
- Colorectal Cancer Fact Sheet

Brochure:
- Women and Colorectal Cancer; also available in Spanish

From the Prevent Cancer Foundation
http://preventcancer.org/colorectal3c.aspx?id=1036

Fact Sheets:
- Colorectal Cancer (also available in Spanish)

From the American Cancer Society
http://www.cancer.org/colonmd

Clinician's Information Source:
- Brochures, DVDs, wall charts

http://caonline.amcancersoc.org/cgi/content/full/57/6/354

• Journal article summarizing this guide

http://caonline.amcancersoc.org/cgi/content/full/CA.2007.0017v1

• Journal article summarizing recent Colorectal Guidelines

From the Agency for Healthcare Research and Quality

http://www.ahrq.gov/ppip/healthymen.htm
http://www.ahrq.gov/ppip/healthywom.htm

Health Checklist

• Health Checklist for men and women

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Consider the Facts:

- Colorectal cancer (CRC) is the second leading cause of cancer mortality in the United States, even though it is largely preventable through screening and polypectomy.
- A doctor's recommendation has the greatest influence on a patient's likelihood of completing screening.
- Less than 50 percent of the population has had one of the recommended screening tests.
- There are proven approaches that can help doctors screen all eligible patients.
- Most primary care physicians believe a substantial proportion of their own patients are not screened.
- Members of minority groups are less likely to be screened.
- A significant percentage of patients with a positive screen never receive a complete diagnostic evaluation.
- Colorectal cancer generated some of the highest malpractice awards in 2004.
- Quality guidelines require that health plans now publicly report CRC screening rates.
- Practice improvements that raise screening rates can earn Continuing Medical Education credit.

Highlights of this Guide

- **Four essentials for improved screening rates**
- **Current screening guidelines**
- **How to overcome screening barriers**
- **The screening practices of primary care physicians**
- **Tools for your practice**

This manual is available online at www.cancer.org/colonmd and www.nccrt.org.